Indiana State Department of Health

LTC Newsletter

LTC & ICF/MR HOMES

Volume 5, Issue 2 *Division of Long Term Care Publication* *July 2005*

Inside This Issue

Governor Appoints State Health Commissioner

The Indiana State Department of Health welcomed Judy Monroe, M.D. as its new state health commissioner on Monday, March 7, 2005.

"It is an honor to be the new state health commissioner and be offered the opportunity to work with this great staff," said Dr. Monroe. "Public health is so important to improving the health of the residents of Indiana and I admire (the staff's) dedication to continued progress."

George Murff of the ISDH's Office of Public Affairs welcomes Dr. Judith Munroe.

Appointed by Governor Mitch Daniels, Dr. Monroe's accomplishments include serving as a successful rural, university and community hospital clinician, educator and executive. She is also an accomplished strategist, scholar, educator and business leader.

During the press conference announcing Dr. Monroe's appointment, Gov. Daniels said, "Judy and I share a vision for improving the quality of life in Indiana by helping Hoosiers incorporate healthy habits into their routines."

During an Indiana State Department of Health Executive Board meeting following the appointment, Chairman Robert E. Currie, DDS said, "I am very pleased….this is an outstanding appointment."

Prior to her appointment, Dr. Monroe was the director of the Primary Care Center and Family Medicine Residency Program at St. Vincent Hospitals and Health Services, Inc. in Indianapolis.

Her professional experience also includes serving as the director of clinics with the Indiana University School of Medicine Department of Family Medicine from 1990 to 1992.

She also spent four years (1986 to 1990) with the National Health Service Corps, Morgan County Regional Health Center in Morgan County Tennessee; and three years (1976 to 1979) at the Walter Reed Army Medical Center in Washington, D.C.

Dr. Monroe received her bachelor's degree from Eastern Kentucky University in 1975, and her M.D. from the University of Maryland in 1983. She also completed a family medicine residency at the University of Cincinnati in 1986, a fellowship in rural faculty development at East Tennessee State University in 1990, and a mini-fellowship in obstetrics at the University of Wisconsin in 1993.

Dr. Monroe resides in Carmel, Indiana with her husband Robert Lubitz, M.D. and three children. ?

Inserts This Issue

National Provider Identifiers

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services (HHS) adopt a standard unique health identifier for health care providers. On January 23, 2004, HHS published the Final Rule that adopts the National Provider Identifier (the NPI) as the standard unique health identifier for health care providers. The effective date of the rule is May 23, 2005, 16 months after its publication date. Health care providers may apply for NPIs beginning on the effective date.

The compliance date for all covered entities is May 23, 2007, except that small health plans do not need to comply until May 23, 2008. When the NPI is implemented, covered entities will use only the NPI to identify health care providers in all standard transactions. Legacy identification numbers (e.g., UPIN, Blue Cross and Blue Shield Numbers, CHAMPUS Number, Medicaid Number, etc.) will not be permitted. Health care providers will no longer have to keep track of multiple numbers to identify themselves in standard transactions with one or more health plans. However, the Taxpayer Identifying Number may need to be reported for tax purposes as required by the implementation specifications.

The NPI is a numeric 10-digit identifier. It is accommodated in all standard transactions, and contains no embedded information about the health care provider that it identifies. The assigned NPI does not expire; and at the current rate of health care provider growth, can continue to be assigned for 200 years. All health care providers, as defined in 45 CFR 160.103, are eligible for NPIs. Health care providers who transmit any health information in electronic form in connection with a transaction for which the Secretary has adopted a standard are covered entities (45 CFR 160.103) and are required to obtain and use NPIs. Health care providers who are not considered covered entities may also apply and be assigned an NPI. However, entities that do not provide health care (e.g., transportation services) are not eligible to be assigned NPIs because they do not meet the definition of "health care provider" and are not subject to HIPAA regulations.

In certain situations, it is possible for "subparts" of organization health care providers (such as hospitals) to be assigned NPIs. These subparts may need to be assigned NPIs in order to conduct standard transactions on their own behalf or to meet Federal regulatory requirements related to their participation in health plans such as Medicare. The Final Rule requires covered health care providers to determine if they have subparts that may need NPIs and, if so, to obtain NPIs for the subparts or require the subparts to obtain their own NPIs. The subpart concept does not pertain to health care providers who are individuals.

Health care providers will be assigned NPIs upon successful completion of an application form. The form can be submitted on paper or over the Internet. Once a health care provider has been assigned an NPI, it must furnish updates to its data within 30 days of any changes. The National Provider System (NPS), being built under a Centers for Medicare & Medicaid Services (CMS) contract, will process the applications and updates, ensure the uniqueness of the health care provider, and generate the NPIs. The NPS will be able to produce reports and information based on requests from the health care industry and others. A single entity, known as the enumerator, and performing under a CMS contract, will operate the NPS. The enumerator will receive applications and updates from health care providers. The enumerator will assist health care providers in completing applications and in furnishing updates, and will be responsible for resolving problems and answering questions. The enumerator will notify the health care providers of their NPIs. The enumerator will also process requests for, and disseminate information containing, health care providers' NPIs. HHS will prepare a Federal Register Notice describing the NPS data dissemination policy.

Information about NPI implementation, including information on how to apply for NPIs, will be made available to the health care industry by CMS closer to the effective date. To learn more, visit CMS's HIPAA website at www.cms.hhs.gov/hipaa/hipaa2. Go to the Administrative Simplification section and search for NPI topics and Frequently Asked Questions. If you have questions you may email them to ASKHIPAA@cms.hhs.gov or call the HIPAA hotline toll free at 1-866-282-0659. ?

The Centers for Medicare and Medicaid Services announces the following plans for transitioning to the National Provider Identifier (NPI) in the Fee-for Service Medicare Program:

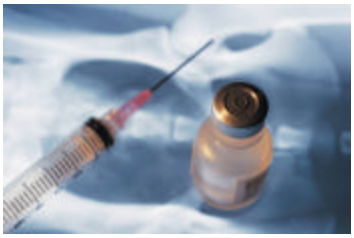
- **Between May 23, 2005 and January 2, 2006, CMS claims processing systems will accept an existing legacy Medicare number and reject, as unprocessable, any claim that includes only an NPI.**
- **Beginning January 3, 2006, and through October 1, 2006, CMS systems will accept an existing legacy Medicare number or an NPI as long as it is accompanied by an existing legacy Medicare number.**
- **Beginning October 2, 2006, and through May 22, 2007, CMS systems will accept an existing legacy Medicare number and/or an NPI. This will allow for 6-7 months of provider testing before only an NPI will be accepted by the Medicare Program on May 23, 2007.**
- **Beginning May 23, 2007, our systems will only accept an NPI .**

For additional information, to complete an NPI application, and to access educational tools, visit https://nppes.cms.hhs.gov on the web.

Recommended Practices and Medical Management For Prevention of Patient-To-Patient Transmission of Hepatitis Viruses From Diabetes Care Procedures

Diabetes Care Procedures and Techniques

- Prepare medications such as insulin in a centralized medication area; multidose insulin vials should be assigned to individual patients and labeled appropriately.
- Never reuse needles, syringes, or lancets.
- Restrict use of fingerstick capillary blood sampling devices to individual patients.
- Consider using single-use lancets that permanently retract upon puncture.
- Dispose of used fingerstick devices and lancets at the point of use in approved sharps containers.
- Assign separate glucometers to individual patients. If a glucometer used for one patient must be reused for another, the device must be cleaned and disinfected. Glucometers and other environmental surfaces should be cleaned regularly and whenever contamination with blood or body fluids occurs or is suspected.



- Store individual patient supplies and equipment, such as fingerstick devices and glucometers, within patient rooms when possible.
- Keep trays or carts used to deliver medications or supplies to individual patients outside patient rooms. Do not carry supplies or medications in pockets.
- Because of possible inadvertent contamination, unused supplies and medications taken to a patient's bedside during fingerstick monitoring or insulin administration should not be used for another patient.

Hand Hygiene and Gloves

- Wear gloves during fingerstick blood glucose monitoring, administration of insulin, and any other procedure involving potential exposure to blood or body fluids.
- Change gloves between patient contacts and after every procedure that involves potential exposure to blood or body fluids, including fingerstick blood sampling. Discard gloves in appropriate receptacles.
- Perform hand hygiene (i.e., hand washing with soap and water or use of an alcohol-based hand rub) immediately after removal of gloves and before touching other medical supplies intended for use on other patients.

Medical Management

- Regularly review patient schedules for fingerstick blood glucose sampling and insulin administration and reduce the number of percutaneous procedures to the minimum necessary for appropriate medical management of diabetes and its complications.
- Ensure that adequate staffing levels are maintained to perform all scheduled diabetes care procedures, including fingerstick blood glucose monitoring.
- Consider diagnosis of acute viral hepatitis infection in patients with illness that includes hepatic dysfunction or elevated liver transaminases (serum alanine aminotransferase and aspartate aminotransferase).
- Provide a full hepatitis B vaccination series to all previously unvaccinated staff members with exposure to blood or body fluids. Check and document postvaccination titers 1-2 months after completion of the vaccination series.
- Establish responsibility for oversight of infection control activities. Investigate and report any suspected case of newly acquired bloodborne infection.
- Require staff members to know standard precautions and demonstrate proficiency in taking these precautions with procedures involving potential blood or body fluid exposures.
- Provide staff members who perform percutaneous procedures with infection control training that includes practical demonstration of aseptic techniques and instruction regarding reporting exposures or breaches. Conduct annual retraining of all staff members who perform procedures with exposure to blood or body fluids.
- Assess compliance with infection control recommendations (e.g., hand hygiene or glove changes) by periodic observation of staff and tracking use of supplies. ?

New State Law Regarding Release of Social Security Numbers

Senate Enrolled Act 530, which adds IC 4-1-10 as a new chapter to the Indiana Code, and which becomes effective June 30, 2006, significantly limits the ability of state government to disclose Social Security numbers in its public records. In anticipation of the implementation of this law, the Indiana State Department of Health, Division of Long Term Care ("Division"), requests that Social Security numbers not be included on any form or in any correspondence addressed to the Division, unless expressly required. In cases where state or federal forms require the disclosure of Social Security numbers, the Division is, effective immediately, redacting (permanently obscuring) this information from all documents prior to inclusion in public record. ?

ISDH Welcomes New Program Director-Provider Services

Seth A. Brooke became the Program Director-Provider Services for the Indiana State Department of Health's Division of Long Term Care on May 23, 2005, Mr. Brooke's first experience working with the Department of Health. Previously, he had been employed in the public sector within a diverse array of settings. From late 2002 until the end of 2003, Mr. Brooke served as an early childhood educator for the City of St. Louis, Missouri at Jefferson Elementary School. He had the good fortune to be one of the primary educators of about sixty children. Then, for the next two years, he worked as a Special Projects Assistant for the City of Bloomington, Indiana. In this capacity, Mr. Brooke assisted as an event planner, commission facilitator, and non-profit organization liaison. Also during this period, Mr. Brooke worked as an analyst intern for the United States Government Accountability Office (GAO). In this position, he acted as an auditor of program performance and accessibility for the United States Congress. Mr. Brooke holds a Bachelors of Arts degree from Purdue University (West Lafayette, Indiana) and a Masters of Public Affairs from Indiana University's School of Public and Environmental Affairs (Bloomington, Indiana). Mr. Brooke may reached at 317/233-7794, or at sbrooke@isdh.state.in.us. ?

Web Sites of Note

Indiana State Department of Health Web Page
http://www.in.gov/isdh/

Health Care Regulatory Services Commission Web Page
http://www.in.gov/isdh/regsvcs/providers.htm

Certified Nurse Aide Registry
http://www.in.gov/isdh/regsvcs/ltc/cna.htm

Consumer Guide to Nursing Homes
http://www.in.gov/isdh/regsvcs/ltc/profile/index.htm

CNAs with Verified Findings
http://www.in.gov/isdh/regsvcs/ltc/badcna/index.htm

Health Care Financing Administration
http://www.in.gov/isdh/regsvcs/ltc/hcfalink/index.htm

How to Read a Survey
http://www.in.gov/isdh/regsvcs/ltc/readsurvey/index.htm

ICF/MR Facility Directory
http://www.in.gov/isdh/regsvcs/ltc/icfmrdir/index.htm

Laws, Rules, and Regulations
http://www.in.gov/isdh/regsvcs/ltc/lawrules/index.htm

Long Term Care Facilities Director
http://www.in.gov/isdh/regsvcs/ltc/directory/index.htm

LTC Newsletters
http://www.in.gov/isdh/regsvcs/acc/newsletter/index.htm

MDS Bulletins
http://www.in.gov/isdh/regsvcs/ltc/mds/index.htm

Non-Cert. Comp. Care Facility Dir.
http://www.in.gov/isdh/regsvcs/ltc/nccdir/index.htm

Nurse Aide Training Guide
http://www.in.gov/isdh/regsvcs/ltc/naguide/index.htm

Nurse Aide Training Sites
http://www.in.gov/isdh/regsvcs/ltc/natdir/index.htm

Nursing Home Compare (CMS)
http://www.medicare.gov/nhcompare/home.asp

Questions About Healthcare
http://www.in.gov/isdh/regsvcs/ltc/questions/index.htm

Report Cards
http://www.in.gov/isdh/regsvcs/ltc/reportcard/index.htm

Reporting a Complaint
http://www.in.gov/isdh/regsvcs/ltc/complaints/index.htm

Residential Care Facilities Directory
http://www.in.gov/isdh/regsvcs/ltc/resdir/index.htm

Retail Food Establishment Sanitation
http://www.in.gov/isdh/regsvcs/foodprot/pdf/410_iac_7-20.pdf

Requirements, Title 410 IAC 7-20
State Operations Manual
http://www.in.gov/isdh/regsvcs/ltc/somanual/index.htm

TB Skin Testing Courses
http://www.in.gov/isdh/programs/tb/tb_train.htm

Access Indiana
http://www.in.gov/

Indiana Secretary of State
http://www.in.gov/sos/

State Forms Online PDF Catalog
http://www.state.in.us/icpr/webfile/formsdiv/index.html

Centers for Medicare and Medicaid Services
http://www.cms.hhs.gov/ or http://www.hcfa.gov/

AdminaStar Federal
http://www.adminastar.com/anthem/affiliates/adminastar/index.html

Family and Social Services Administration – Aging:
http://www.in.gov/fssa/elderly/

Family and Social Services Administration – Healthcare
http://www.in.gov/fssa/healthcare/

Indiana Medicaid
http://www.indianamedicaid.com/ihcp/index.asp

US Government Printing Office
http://www.gpo.gov/

Indiana State Police
http://www.in.gov/isp/

MDS Web Site
http://www.hcfa.gov/medicaid/mds20/

Indiana State Department of Health

LTC News is published by the
Indiana State Department of Health
Division of Long Term Care
2 N. Meridian Street
Indianapolis, IN 46204-3006

Judith A. Monroe, MD
State Health Commissioner
Sue Uhl, JD
Deputy State Health Commissioner
Terry Whitson, JD
Assistant Commissioner
Health Care Regulatory Services
Suzanne Hornstein, MSW
Director of Long Term Care
Stephen Upchurch, BS
Editor

Indiana State Department Of Health
Division of Long Term Care

TELEPHONE GUIDE

Arranged alphabetically by subject

All are Area Code 317

SUBJECT	CONTACT PERSON	EXTENSION
Administrator/DON, Facility Name/Address Changes	Seth Brooke	233-7794
Bed Change Requests (Changing/Adding Licensed Bed/Classifications)	Seth Brooke	233-7794
CNA Registry	Automated	233-7612
CNA Investigations	Zetra Allen	233-7772
CNA/QMA Training	Nancy Adams	233-7480
Criminal History		
Director, Division of Long Term Care	Suzanne Hornstein	233-7289
Enforcement & Remedies	Stephen Upchurch	233-7613
Facility Data Inquiries	Sarah Roe	233-7904
FAX, Administration		233-7322
Incidents/Unusual Occurrences	Fax Voicemail Other	233-7494 233-5359 233-7442
Informal Dispute Resolution	Susie Scott	233-7651
License/Ownership Verification Information	Seth Brooke	233-7794
License Renewal	Seth Brooke	233-7794
Licensed Facility Files (Review/Copies)	Darlene Jones	233-7351
Licensure & Certification Applications/Procedures (for New Facilities and Changes of Ownership)	Seth Brooke	233-7794
Life Safety Code	Rick Powers	233-7471
MDS/RAI Clinical Help Desk	Kimberly Honeycutt	233-4719
MDS Technical Help Desk	Technical Help Desk Staff	233-7206
Monitor Program	Debbie Beers	233-7067
Plans of Correction (POC), POC Extensions & Addenda	Area Supervisors	See Below
Plans & Specifications Approval (New Construction & Remodeling)	Dennis Ehlers	233-7588
Reporting	Tom Reed	233-7541
Rules & Regulations Questions	Debbie Beers	233-7067
Survey Manager	Kim Rhoades	233-7497
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Unlicensed Homes/Facilities	Jody Anderson	233-7611
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Web Site Information	Sarah Roe	233-7904

AREA SUPERVISORS

Area 1	Judi Navarro	233-7617
Area 2	Brenda Buroker	233-7080
Area 3	Vacant	---
Area 4	Zetra Allen	233-7772
Area 5	Karen Powers	233-7753
Area 6	Pat Nicolaou	233-7441
Life Safety Code	Rick Powers	233-7471
ICF/MR North	Brenda Meredith	233-7894
ICF/MR South	Steve Corya	233-7561

Updated 6/2005

Mitchell E. Daniels, Jr.
Governor

Judith A. Monroe, M.D.
State Health Commissioner

Indiana State Department of Health

An Equal Opportunity Employer

ISDH Program Guidance Letter
Number: LTC-2005-01
Effective Date: June 1, 2005
Cancels: n/a
Revised: n/a

DATE: June 1, 2005

TO: Administrators of Indiana Comprehensive and Residential Care Facilities

SUBJECT: Alzheimer's and dementia care annual training requirement for comprehensive and residential care facilities

Letter Summary

- The three hour annual dementia specific training requirement will be based on a calendar year.
- The three hour annual dementia-specific training requirement begins in the year following the employee's date of hire.
- Upon the request of a current employee, former employee, or health facility, the ISDH requests that health facilities provide a copy of an employee's dementia specific training records.

Purpose:

The purpose of this memorandum is to provide Indiana comprehensive and residential care facilities with guidance relating to the implementation of the annual training requirement for the Alzheimer's and dementia care training rule. The issue concerns the health facility implementation and documentation of the three hour annual dementia specific training requirement.

Background:

In 2004 the Indiana State Department of Health (ISDH) adopted a rule requiring Alzheimer's and dementia care training for all comprehensive and residential care staff having regular contact with residents. The rule [410 IAC 16.2-3.1-14(u) for comprehensive care and 410 IAC 16.2-5-1.4(e)(2) for residential care facilities] requires six hours of dementia specific training within six months of initial employment or within thirty days for personnel assigned to the Alzheimer's and dementia special care unit. The rule then requires three hours of training annually thereafter to meet the needs and preferences of cognitively impaired residents and to gain understanding of the current standards of care for residents with dementia.

The rule became effective August 22, 2004. In previous communications, the ISDH set November 22, 2004 as the implementation date for completion of initial training for staff working in an Alzheimer's and dementia special care unit. The ISDH set February 22, 2005 as the implementation date for completion of initial training of staff not working in a special care unit.

Since February 22, 2005, the ISDH has received numerous inquiries concerning the implementation of the three hour annual training requirement. A common question has been when the annual training cycle begins and ends – i.e. is it based on the hire date, the date of the initial training, the 30-day or six-month date, or calendar date. A second common question concerns the surveying of the dementia-specific training rule.

Policy and Procedure:

The ISDH will survey facilities for compliance with the Alzheimer's and dementia care training rule using a calendar year training period. A facility must provide the initial dementia specific training within the required 30-day or six-month period from the hire date as specified in the rule. The three (3) hour annual trainings apply to and begin with the year following the hire date. The same training cycle applies to the training requirements for the special care unit director under 410 IAC 16.2-3.1-13(w) and 410 IAC 16.2-5-1.3(l).

Health facilities are required to maintain records of in-service trainings [410 IAC 16.2-3.1-14(o)(p)(q) and 410 IAC 16.2-5-1.4(e)(3) and (h)]. The health facility is therefore required to maintain documentation of dementia specific training. The goal of the dementia specific training requirement is to ensure that all employees receive training concerning care of residents with Alzheimer's or dementia. As much as possible, the ISDH hopes to eliminate unnecessary duplication of training. Upon the request of a current employee, former employee, or health facility, the ISDH requests that health facilities provide a copy of an employee's dementia specific training records. This will assist in promoting an efficient and effective system and assist all facilities in ensuring employee compliance with the rule requirements.

Discussion:

Training cycles

Several health facility administrators or directors of nursing requested that the ISDH adopt a simple and consistent standard for dementia specific training cycles. If the training cycle were to be based on the actual date of training or forever be based on the hire date, a health facility would potentially have a different training cycle for every employee. Many persons expressed a concern that maintaining individual training cycles for every employee would be unduly confusing and burdensome. The goal of the ISDH is to standardize and simplify the training cycle for annual dementia specific training. The use of a calendar year cycle appears to be the simplest solution. The following are examples of the cycle.

1. An employee was hired prior to the rule effective date of August 22, 2004. The employee does not work in a special care unit. The employee received the initial six-hour Alzheimer's and dementia care training on December 1, 2004. Based on a hire date of December 31, 2004 or before, the annual training requirement begins in 2005. The employee must receive three hours of Alzheimer's and dementia specific training between January 1, 2005 and December 31, 2005 and every calendar year thereafter.

2. An employee was hired prior to the rule effective date of August 22, 2004. The employee does not work in a special care unit. The employee received the initial six-hour Alzheimer's and dementia care training on February 10, 2005. Note that the training was provided within the six-month requirement proscribed in the rule. Based on a hire date of December 31, 2004 or before, the annual training requirement begins in 2005. In addition to the six-hour initial training provided on February 10, 2005, the employee must receive three hours of dementia specific training between January 1, 2005 and December 31, 2005 and every calendar year thereafter.

3. An employee is hired on January 2, 2005 and is assigned to the special care unit. The employee must receive the initial six hour Alzheimer's and dementia care training on or before February 1, 2005. Based on the hire date of January 2, 2005, the three hour annual training requirement begins in 2006. The employee must therefore receive three hours of Alzheimer's and dementia specific training between January 1, 2006 and December 31, 2006 and every calendar year thereafter.

4. An employee is hired on December 30, 2005. If the employee is assigned to the special care unit, the employee must receive the initial six hour Alzheimer's and dementia care training on or before January 28, 2006. If not assigned to the special care unit, the employee must receive training on or before June 29, 2006. Based on the hire date of December 30, 2005, the three hour annual training requirement begins in 2006. In addition to the initial six-hour training that will likely occur in 2006, the employee must also receive three hours of Alzheimer's and dementia specific training between January 1, 2006 and December 31, 2006 and every calendar year thereafter.

Survey procedures

Another question received by the ISDH concerns how the ISDH will survey for compliance with this rule. During a survey, the surveyors will review a sample of staff training records to determine compliance with the dementia specific training requirements.

Health facilities are expected to have documentation of dementia specific training for each employee. Surveyors will review the documentation to ensure compliance with the rule. If questions arise as to the validity of the documentation, the surveyors may further investigate to determine whether the documentation is an accurate representation of the training received by an employee.

Providing and accepting training

A facility should document training according to facility policy. For training provided by a health facility, the ISDH recommends that each employee be given a certificate of completion stating the date of training, title of training provided, the training instructor, and hours earned. A copy of the certificate should be maintained in the facility's records.

The ISDH appreciates that employees occasionally switch employers or work for multiple employers. The purpose of the rule is to ensure that health facility personnel have training in Alzheimer's and dementia care. The ISDH interprets this rule as to avoid unnecessary duplication of training and encourage training obtained from a variety of sources. To achieve that purpose, upon the request of a current employee, former employee, or health facility, the ISDH requests that health facilities provide a copy of an employee's dementia specific training records. A facility may, but is not required to, accept dementia specific training provided by other providers or organizations.

Action Required of a Health Facility:

Health facilities must ensure that documentation of each employee's dementia specific training is contained in the health facility's records. The health facility must ensure that each employee has received the dementia specific annual training within a calendar year.

Effective Date:

The information containing in this memorandum clarifies current policy and is implemented upon distribution.

Training:

The information contained in this announcement should be shared with health facility administrators, directors of nursing, directors of special care units, and corporate compliance officers.
For questions concerning this program letter, please contact the ISDH Director of Long Term Care, Sue Hornstein, at 317-233-7289 or shornste@isdh.state.in.us; or ISDH Public Health Nurse Surveyor, Debbie Beers, at 317-233-7067 or dbeers@isdh.state.in.us.

Cordially,

/s/

Terry L. Whitson
Assistant Commissioner
Health Care Regulatory Services Commission
Indiana State Department of Health
Phone: 317-233-7022
twhitson@isdh.state.in.us

Enc: none
cc: ISDH survey staff

THE AMERICAN HEALTH QUALITY ASSOCIATION

Advancing the Safety and Quality of Health Care Nationwide

NEWS RELEASE

For Immediate Release
May 19, 2004

Contact: David Adler
202-261-7572

QIOs to Help Reduce Staff Turnover in Nursing Homes
National Commission Calls For Action On Staff Shortages

Washington, D.C. –-Quality Improvement Organizations (QIOs) will begin working this summer to help reduce staff turnover in nursing homes across the country. QIOs will undertake this effort as part of a new three-year contract with the Centers for Medicare & Medicaid Services (CMS).

The contract calls for QIOs to cut nursing assistant turnover rates by at least 15% in over 2,000 nursing homes by late-2007. Reducing nursing home staff shortages is the focus of a report, "Act Now For Your Tomorrow," released today by the National Commission on Nursing Workforce for Long-Term Care. The commission reported that on any given day there are almost 100,000 vacant nursing staff positions in long-term care facilities. Staff turnover in many facilities exceeds 50% annually. The diverse members of the Commission were brought together by the American Health Care Association, which represents thousands of long-term care facilities and has been a national leader in drawing attention to nurse staffing shortages.

"The high level of staff turnover in nursing homes is corrosive to personal relationships that are important to both nursing home residents and workers. Turnover directly detracts from the quality of health care for residents and raises the cost of providing care," said David Schulke, Executive Vice President of the American Health Quality Association, which represents the national network of QIOs—private organizations that work in every state to improve the quality of care.

"Poor retention leads to understaffing and stressed-out nursing staff who must rush to provide very personal care to prevent pressure sores, feeding, bathing and assisting with toileting. It leads to caregivers who don't know the residents, who are always strangers," Schulke said. "Nurse aide turnover averages 71% per year. Reducing nursing aide turnover by at least 15% over the next three years will save about $27,000 per home per year -- enough money to hire an additional nurse aide. Or it could finance professional development training opportunities, as recommended in the Commission report."

Helping Reduce Staff Turnover

Schulke spoke at a Washington news conference to release the report, which recommends state and local initiatives to help reduce the long-term care nursing shortage, but says that successful staff retention depends largely on "work by long-term care nursing leaders to improve their internal organization and operation."

QIOs will work in a number of ways to help nursing home leaders succeed in creating working conditions that reduce turnover, Schulke said.

- QIOs will help nursing home management learn to measure staff and resident satisfaction data and turnover rates, and to routinely use these as organizational management techniques.
- QIOs will help nursing home managers adopt the practice of assigning the same aides to the same residents every time they come to work—a critical step for improving care, strengthening caregiver-resident relationships, and reducing turnover. Experts in the field estimate as few as 5% of nursing homes are using consistent assignment today; the current norm is to constantly rotate staff through different facility wards.
- QIOs will help nursing home managers work with staff closest to the problems to help design solutions. Experience has shown that nurses and nurse aides often come up with creative solutions that work, and that being part of the solution increases job satisfaction.
- QIOs will customize the training agenda in workshops and onsite interventions to focus on issues commonly cited by staff—from dissatisfaction with salary and schedules to issues of personal worth and fulfillment, such as having opportunities to learn and grow professionally, the freedom to work in non-hierarchical teams, and feeling valued, respected and informed by licensed nurses and management.
- QIOs will encourage nursing home executives and clinical leaders to improve management practices to empower nurse aides and enhance their relationships with residents through consistent assignment, team-building, recognizing high performance by workers, and simple but meaningful steps like recognizing and honoring grief when a resident dies.

CMS is also asking QIOs to make significant improvements in clinical care for nursing home residents—including significant reductions in numbers of residents with pressure ulcers and helping nursing homes improve patient assessments and other processes of care—a continuation of QIO efforts over the past three years.

Building On Prior Success

Schulke pointed out that during the last three years, QIOs have been major contributors to the national Nursing Home Quality Improvement initiative started and funded by CMS.

Partnering with nursing homes, QIOs have taught best practices and provided assistance to help improve care as measured by standardized quality indicators. This work has demonstrated some significant early results, announced by CMS last December, including nationwide gains in reducing the numbers of residents suffering from pain and residents who are physically restrained.

CMS data shows that the 2,500 nursing homes that worked more intensively with their QIOs have improved faster than the national trends.

The Rhode Island QIO, working on a pilot project with 10 multi-facility corporations, is currently conducting educational sessions with senior administrative leadership and direct care workers to implement ways to improve nurse satisfaction and reduce turnover. This collaborative learning method stresses peer-to-peer education and information sharing on best practices, and it has already shown promising results that QIOs will build upon nationwide.

The American Health Quality Association is dedicated to improving the safety and effectiveness of health care. AHQA represents the national network of Quality Improvement Organizations (QIOs) that work with hospitals, medical practices, health plans, long-term care facilities, home health agencies, and employers to encourage the spread of best clinical practices and improve systems of care delivery.

Health Care Excel

Medicare Quality Improvement Organization (QIO) for Indiana

The Medicare QIO is inviting nursing homes in Indiana to work closely with us in the next phase of the CMS's Nursing Home Quality Initiative (NHQI). Over the past 2 ½ years of the NHQI, improvements have occurred and successes were achieved by many nursing homes throughout the state with an even greater rate of improvement with the nursing homes that worked closely with the Medicare QIO on this initiative.

The Medicare QIO will continue to work with nursing homes throughout Indiana to improve care and the quality of life of our most vulnerable population. The QIO will provide education, assistance, and resources to help providers evaluate their care processes, their work place practices, and their environment to identify areas for improvement. The Medicare QIO's improvement work will address four quality measures; chronic pain, depression, high-risk pressure ulcers, and restraints through a transformational change approach called person centered care. This approach intends to lead nursing homes to improved quality of care and quality of life for residents, improved staff satisfaction, and reduction in staff turnover.

CMS is encouraging nursing homes throughout the nation to submit target goals for improving their quality measure results in pressure ulcers, restraint use, depression, and pain management. These targets will be submitted annually through use of a tool called **STAR** (Setting Targets—Achieving Results). The Medicare QIO will be providing as many of 15 to 20 meetings throughout the state to educate nursing homes about setting target goals. Nursing homes are volunteering to host these educational meetings in August and September. Dates and locations will be available soon. Invitations will be faxed and mailed.

For further information about joining the NHQI with the Medicare QIO or interest in the STAR training, please contact the Medicare Provider Help Desk at 1-800-300-8190, or e-mail innursinghome@hce.org.

The Nursing Home STAR Site

Setting Targets—Achieving Results

The following information introduces you to a Web site that will be available for free to volunteer nursing homes nationwide beginning in August 2005.

Background

The Setting Targets—Achieving Results (STAR) Web site helps nursing homes incorporate the publicly reported quality measure data into their own internal quality improvement efforts. Upon login to the STAR site, a nursing home can view trend reports for four quality measures and then set goals for up to one year (i.e., four quarters). The site focuses on depression, pain, pressure ulcers, and physical restraints.

Nursing homes interested in using the STAR site should contact the Medicare Quality Improvement Organization (QIO) for Indiana by calling the Medicare QIO Provider Help Desk at 1-800-300-8190 or e-mailing innursinghome@hce.org.

Purpose

The purpose of the STAR site is to help nursing homes use their publicly reported nursing home quality measures to set internal quality improvement goals. To help nursing homes use targets to improve the quality of care provided, each state QIO will provide its nursing homes with a STAR Toolkit containing helpful materials. For example, the toolkit will include posters to post and track trend reports, as well as to publicize targets throughout the facility.

Using the STAR Site

After login to the STAR site using a secure login process, nursing homes will see their quality measure trend reports and be able to compare their quality measure scores to state and national averages. The site will then present nursing homes with several target-setting methods (e.g., a 10 % reduction) and guide each nursing home through the process of identifying appropriate goals.

Once nursing homes choose targets and submit them, these targets appear on their trend reports for up to one year (i.e., four quarters). The trends reports allow the home to track its progress toward achieving the targets. If the home is successful in achieving the targets or wants to change the targets before they expire, staff can submit new targets as frequently as once a quarter.

The STAR site is intended for nursing homes' internal use only. Nursing homes may set targets of any value.

Targets will not be shared with State Survey and Certification Agencies, unless the nursing home gives its QIO written permission. CMS will see aggregate targets (e.g., state and national averages), but will not see any individual facility data or know which facilities use the STAR site.

Requirements

To use the STAR site, nursing homes will need computers with Internet connections. Any Internet connection will work, including a modem line; however, a faster connection (such as DSL) will allow the nursing home to view graphs and information more easily.

Computers are becoming increasingly important to the provision of high-quality health care. To use the STAR site, you will need access to a computer and an Internet connection.

This material was prepared by Quality Partners of Rhode Island, the Medicare Quality Improvement Organization for Rhode Island, and adapted by Health Care Excel, the Medicare Quality Improvement Organization for Indiana, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 7SOW-IN-NH-05-106 HCEI 05-2005

Nursing Home Improvement and Feedback Tool (NHIFT)

The following information introduces you to a free computer-based tool that will be available to interested volunteer nursing homes nationwide in January 2006.

Background

The Nursing Home Improvement and Feedback Tool (NHIFT, pronounced "nifty") is an electronic data collection tool consisting of a series of questions related to processes of care for five clinical topic areas: depression, immunizations, pain, pressure ulcers, and physical restraints. In January 2006, NHIFT will be available for free to interested nursing homes through the Quality Improvement Organization (QIO) Program.

Nursing homes interested in using the NHIFT should contact the Medicare Quality Improvement Organization (QIO) for Indiana by calling the Medicare QIO Provider Help Desk at 1-800-300-8190 or e-mailing innursinghome@hce.org.

Purpose

NHIFT is an internal quality improvement tool that enables the nursing home to do the following:

? Abstract medical record data for new admissions each month
? Track adherence to recommended care processes (based on clinical guidelines) for five clinical topics
? Compare adherence to acceptable processes of care with other nursing homes' aggregate data
? Guide care by identifying recommended processes

Using the NHIFT

Use of NHIFT is strictly voluntary and is intended for nursing homes' internal use. Installed on nursing homes' PC workstations, the NHIFT computer application lets staff select which process of care measures to calculate, and then provides a series of questions to answer in order to calculate those measures. Staff answer these questions by submitting information found in residents' medical records.

The process measures available in 2006 will focus on recently admitted residents; users of NHIFT will be asked to submit data quarterly on all new admissions. After submission, the nursing home will receive a data comparison report showing the facility's scores and a comparison group (e.g., national and state averages for each measure). Future enhancements to the tool may include the ability for facilities to compare their process measures to other nursing homes' scores based on criteria such as bed size or ownership.

The NHIFT process data are intended for nursing homes' internal use only. They will not be shared with State Survey and Certification Agencies, unless the nursing home gives its QIO written permission. CMS will see aggregate targets (e.g., state and national averages), but will not see any individual facility data or know which facilities use NHIFT.

System Requirements

To install NHIFT, it is recommended that nursing homes have PC workstation computers with at least the following.*

500 MHZ processor
256 megabytes of RAM
1 gigabyte hard drive space available
Windows 2000
Pentium 3

*These are the same suggested requirements necessary to upgrade your system for RAVEN.

Computers are becoming increasingly important to the provision of high-quality health care. To use NHIFT, you will need access to a computer with the above specifications.

This material was prepared by Quality Partners of Rhode Island, the Medicare Quality Improvement Organization for Rhode Island, and adapted by Health Care Excel, the Medicare Quality Improvement Organization for Indiana, under contract with the Centers for Medicare & Medicaid Services (CMS), an agency of the U.S. Department of Health and Human Services. The contents presented do not necessarily reflect CMS policy. 7SOW-IN-NH-05-105 HCEI 05-2005

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
Room 303-D
200 Independence Avenue, SW
Washington, DC 20201

Public Affairs Office

FOR IMMEDIATE RELEASE
March 24, 2005

Contact: CMS External Affairs
(202) 690-6145

CMS TO REQUIRE CERTAIN NURSING HOMES TO INSTALL SMOKE DETECTORS

Nursing homes that do not have sprinkler systems or hard-wired smoke detectors will have to install battery-operated ones in patient rooms and public areas according to an announcement made today by the Centers for Medicare & Medicaid Services (CMS).

"This is an important rule that could save many lives by making real improvements in nursing home safety," said CMS Administrator Mark B. McClellan, M.D., Ph.D. "Nursing home residents are an especially vulnerable population and we need to take every step possible to protect them."

CMS took this unprecedented action after two tragic nursing home fires in Connecticut and Tennessee in 2003. Neither home had smoke detectors in the patient rooms where the fires originated. The agency worked closely with the National Fire Protection Association to develop ways to get effective fire protection into all facilities.

A review of the two incidents by the Government Accountability Office (GAO) asserted that smoke detectors could have resulted in quicker staff response that may have led to a better outcome.

Today's action will considerably improve the safety of residents living in over 4,000 nursing homes that do not have sprinkler systems. Newly constructed nursing facilities are required to be fully covered by a sprinkler system, while older homes built of noncombustible materials like concrete block are not. Homes will be given a year in which to comply with the new requirement.

The NFPA is the group that developed the 2000 edition of the Life Safety Code that CMS uses to set the standard in health care facilities.

Also in today's interim final rule is a provision that will allow nursing homes, hospitals, ambulatory surgical centers and other health care facilities to install dispensers of alcohol-based hand sanitizers in exit corridors that meet certain conditions. This had not been allowed previously because of concerns that the alcohol rubs may serve as an accelerant in the event of a fire and block access to exits. Studies on this concern, however, have shown that if certain conditions are met, that fire hazard is greatly reduced while there can be a significant benefit in reducing hospital-acquired infections.

Alcohol-based hand rubs are more effective at destroying bacteria than ordinary soaps and water. This is critically important in a health care setting. The Centers for Disease Control estimates that two million patients a year get hospital-based infections and that 90,000 of those patients die. Hospital-based infections can often be traced to a lack of hand washing by health care personnel with direct patient contact.

"As a physician, I am very familiar with the important role hand hygiene plays in stopping the spread of infections," said Dr. McClellan. "Increasing the number of these dispensers in and near patient rooms has proven to significantly increase hand cleansing activities by health care professionals and even the patients themselves."

Some precautions facilities must take include making sure the dispensers are not near a heat or ignition source, that they are at least four feet apart and that they are placed in corridors at least six feet wide.

The full interim final rule will be published in the March 25 Federal Register.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations

Ref: S&C-05-19

DATE: February 18, 2005

TO: State Medicaid Agency Directors

FROM: Director
Survey and Certification Group

Director
Disabled and Elderly Health Programs Group

SUBJECT: Release of Long Term Care Minimum Data Set (LTC/MDS) Data to State Medicaid Agencies, Section 1915 Waiver Programs, and "Real Choice Systems Change Grant" Programs in Order to Assist States' Title II, Americans with Disabilities Act (ADA) Compliance Activities.

Letter Summary

- This letter provides guidance on CMS disclosure of LTC/MDS data to State Medicaid Agencies, Section 1915 Waiver Programs, and "Real Choice Systems Change Grant" Programs in order to assist states in their efforts to comply with the integrated care setting and reasonable accommodation requirements of Title II of the ADA.
- This letter should be shared with appropriate state agency staff and designated entities that are working on waiver and grant programs.

Background

The Centers for Medicare & Medicaid Services (CMS) and its state partners have made important strides in identifying and eliminating barriers to community living. Many states are developing and implementing service delivery, financing, and administrative mechanisms to prevent and correct inappropriate placement of individuals in institutions and ensure adequate community supports. By allowing states access to LTC/MDS data, State Medicaid Agencies, Section 1915 Waiver programs, and Real Choice Systems Change Grant Programs can identify and transition LTC residents who would like to, and could appropriately be placed in the community. These ADA requirements have been clarified by the Supreme Court in Olmstead v. L.C., 527 U.S. 581 (1999). For a more detailed discussion of how states might utilize LTC/MDS data to further their Olmstead and ADA programs, please find "In Brief……Using the Minimum Data Set to Facilitate Nursing Home Transition" available at www.communitylivingta.info. This site is funded via a Real Choice Systems Change Grant from CMS to the Community Living Exchange Collaborative. The purpose of this grant is to provide technical assistance to grantees, including facilitating the sharing of information across states. This site is administered by Boston College on behalf of the Community Living Exchange Collaborative.

Data collected through the LTC/MDS is maintained by CMS in accordance with the Privacy Act of 1974. The Privacy Act limits the disclosure of individually-identifiable information held by Federal agencies and permits disclosure of such information only when the purpose of the disclosure is one of the bases for the data collection's establishment, and for specific "routine uses." These "routine uses" are listed in a published (via the Federal Register) System of Records Notice. Routine uses include various purposes such as administration of the Survey and Certification Program, and payment of LTC services, which include skilled nursing facilities (SNFs), nursing facilities (NFs), SNF/NFs, and hospital swing beds, and to study the effectiveness and quality of care provided in those facilities.

Under the Privacy Act provisions, states and/or CMS are required to track disclosures of LTC/MDS data at the beneficiary level. LTC/MDS data releases may be tracked by the state or by CMS.

Use of MDS Data for Compliance with Title II Requirements

If the conditions discussed in this letter are met by the execution of a data use agreement (DUA), CMS will provide State Medicaid Agencies with LTC/MDS data on the residents of that state and beneficiaries of that State's Medicaid program. One purpose of such use is to assist states in their efforts to comply with the integrated care setting and reasonable accommodation requirements of Title II of the ADA. CMS believes that the LTC/MDS data will help states and designated entities identify residents with disabilities who have a desire to live in the community, and will provide information related to the level of services necessary to fulfill states' ADA requirements in relation to such individuals.
In an effort to further assist states in ADA compliance activities, CMS has developed a report providing aggregated current resident responses to the LTC/MDS Section Q1a. The report provides state, and more importantly, county level information on resident responses. This data is available on the CMS Web site at http://www.qtso.com/mdsdownload.html and is updated quarterly.

Obtaining MDS Data

CMS will allow State Medicaid Agencies or designated entities access to LTC/MDS data on the residents and Medicaid beneficiaries of that state after it receives and approves a Medicaid Data Use Agreement (MDUA) from the state. The MDUA must be signed by the requestor and the custodian of the data and binds the parties to the requirements of the Privacy Act and the applicable LTC/ MDS System of Records. CMS has prepared the updated MDUA with ADA provisions and revised the Addendum sheet to include Title II ADA activities. The required forms and other information can be accessed at www.cms.hhs.gov/privacyact/requests .

Completed MDUAs should be submitted to the Regional Office MDS representative for review and approval. States that execute a new or updated MDUA may obtain all state-specific LTC/MDS data for purposes listed in #6 of the MDUA, which include activities aimed at ensuring state compliance with the requirements set forth in Title II of the ADA.

States that request the LTC/MDS data for purposes outside those specified in the MDUA must request a Standard DUA. The Standard DUA is an open-ended agreement that allows the requestor to request LTC/MDS data for other uses. Those uses are also subject to the limitations on use and disclosure of individually identifiable information held in the LTC/MDS System of Records.

States that have already submitted a MDUA for access to the LTC/MDS data may update those agreements to allow for the use of LTC/MDS data in ADA compliance programs. States should complete the Addendum sheet to reflect the custodian's information, signature, and additional use for ADA purposes.

State Medicaid Agencies with new or updated MDUAs and tracking mechanisms may obtain all state-specific LTC/MDS data. States that require assistance with the extraction of data will be charged a fee for each year of MDS data requested.

Technical Assistance

States that have not executed an MDUA and require technical assistance to establish how to comply with tracking requirements may contact Karen Edrington of CMS' Division of National Systems at 410-786-2166 or by email at kedrington@cms.hhs.gov.

/s/
Thomas E. Hamilton

/s/
Gale Arden

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

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DATE: March 10, 2005 Ref: S&C-05-20

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

Letter Summary

- The purpose of this memorandum is to affirm our expectation that when noncompliance with a federal requirement has been identified, the facility or provider will receive a deficiency associated with the noncompliance.
- This memorandum restates existing CMS policy in Appendix P regarding independent but linked deficiency citations.

SUBJECT: All Provider Types - Independent but Associated Deficiency Citations

Attached you will find documents supporting this requirement including:

- Regulatory language that identifies facility compliance requirements; and
- Relevant areas of the State Operations Manual (SOM), Appendix P Task 5C and 6. This guidance addresses the necessity of survey teams to review all requirements in order to determine if there was noncompliance with any of the regulations.

There are instances in which a deficient practice creates noncompliance with more than one regulation. In those situations, noncompliance with each requirement should be cited. This situation may be referred to as "independent but associated" citations. This guidance applies to all provider types.

Some investigative protocols (such as those for pressure ulcers, hydration, and weight loss) include a list of regulations that may or may not be a concern depending upon investigation. The surveyor is expected to conduct further investigation, if concerns are identified, to determine whether non-compliance is present with those additional requirements.

For Example:
If a resident develops avoidable pressure ulcers after admission, the surveyor may make the determination that the facility failed to meet the requirement that a resident entering a facility without a pressure ulcer does not acquire one unless it is unavoidable. In that case, the pressure ulcer (sore) requirement (tag F314) is out of compliance. During the investigation, the surveyor might also find the facility did not conduct a comprehensive assessment of the resident's risk for development of a pressure ulcer. If so, the facility has also failed to comply with the regulatory language at F272. This tag requires a comprehensive assessment and is not specific to just pressure ulcers.

If the facility fails to do a comprehensive assessment of residents in other care areas, these would be combined with the pressure ulcer finding into a citation that describes the facility failure at F272. This example is not simply a matter of referencing noncompliance of one requirement with a second requirement. Rather, it reflects determining two distinct requirements have not been met after conducting a thorough review.

Another facility may have failed to meet the requirement for F314 because the resident developed an avoidable pressure ulcer. During the review the surveyor noted there was not sufficient staff to implement the care plan. In that case, the staffing requirement at F353 would also be out of compliance, since that regulation requires the facility to employ sufficient staff to provide care to the resi-

dents based on their care plan. In these two cases only determining non-compliance with F314 does not account for what the facility failed to do. Equally important, it does not inform the facility of the problems they need to fix.

In General:
Cite to the regulatory language, summarizing or describing the deficient practice as it relates to the requirement:

- If the failure led to a negative or potentially negative outcome, cite the appropriate outcome tag; and

Cite the specific process and/or structure requirement if specific failures in the areas of process or structure are identified through investigation.

While writing the survey finding on Form CMS-2567, it is important to remember that the language for related deficiencies should not merely be repeated. Language should be written at each tag that reflects noncompliance for that specific requirement.

We expect the survey process to be conducted consistent with Federal guidance and the Centers for Medicare & Medicaid Services (CMS) remains committed to monitoring adherence with our program requirements. The expectation that the certification program will be conducted consistent with our guidance is the basis on which the State performance review is conducted.

Concerns:
We have heard from some providers that citation of more than one deficiency for a single type of negative outcome simply represents "piling it on" by states or CMS. The regulations do not support this view. Nor do we agree as a matter of proper management and practice. Often one citation will focus on or manifest cause for a poor outcome, while another citation may focus on a systemic or root cause. It is vital that health care providers address all factors that contribute to negative outcomes.

If you have any further questions or concerns regarding the issues in this letter, please contact Cindy Graunke at (410) 786-6782 or Beverly Cullen at (410) 786-6784.

Effective Date: The information in this memorandum should be shared with survey staff within 30 days of the publication date.

Training: The information contained in this announcement should be shared with all survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

ADDENDUM

The survey process requires surveyors to determine a facility's compliance with the applicable requirements. In order to maintain certification in the Medicare/Medicaid program, nursing homes must be in compliance with all of the regulations. This is in regulation at the following:

42 CFR 483.1 (b) - Scope. The provisions of this part contain the requirements that an institution must meet in order to qualify to participate as a Skilled Nursing Facility (SNF) in the Medicare program, and as a Nursing Facility (NF) in the Medicaid program. They serve as the basis for survey activities for the purpose of determining whether a facility meets the requirements for participation in Medicare and Medicaid.

42 CFR 483.75 (b) - Compliance with Federal, State and local laws and professional standards. The facility must operate and provide services in compliance with **all** applicable Federal, State, and local laws, regulations, and codes, and with accepted professional standards and principles that apply to professionals providing services in such a facility (emphasis added).

42 CFR 488.301 - Definitions. Deficiency means a SNF's or NF's failure to meet a participation requirement specified in the Act or in part 483, subpart B of this chapter.

Excerpts from Appendix P of the State Operations Manual (SOM) –
Survey Protocol for Long Term Care Facilities

The survey process contains specific procedures, which are delineated in the SOM, Appendix P, to provide guidance for a surveyor in how to conduct the standard, extended, revisits and complaint surveys. Within the guidance, in order to promote consistency, investigative protocols have been developed that provide specific processes for the surveyor to utilize in evaluating areas of concern such as the following: Hydration; Unintended Weight Loss; Dining and Food Service; Nursing Services - Sufficient Staffing; Adverse Drug Reactions, and the Abuse Prohibition Protocol. Within each protocol, at the end, is a section titled Task 6, Determination of Compliance. This section provides guidance for the surveyor to investigate regulatory requirements related to the issue that may be out of compliance and to cite deficiencies if negative findings are identified. This section includes a list of several regulatory requirements. An example of the Investigative Protocol – Hydration, is attached for review.

TASK 6 - Information Analysis for Deficiency Determination

A component of the survey process is the decision making by the survey team to determine if the facility is in compliance with **all** the requirements (emphasis added). The surveyors are required to conduct a review of all the requirements as a team to ascertain whether they identified any areas of non-compliance and to delineate the areas of non-compliance that will be cited. For the purpose of this paper, only excerpts of the Task 6, which describe the review of the regulatory requirements, will be attached.

This section also defines a "deficiency as a facility's failure to meet a participation requirement." It should be noted that the guidance states that all regulatory requirements that are deficient may be issued based upon findings. (Please refer to Task 6 in the SOM, Appendix P for the complete version.)

Investigative Protocol
Hydration

Objectives:

To determine if the facility identified risk factors which lead to dehydration and developed an appropriate preventative care plan; and

To determine if the facility provided the resident with sufficient fluid intake to maintain proper hydration and health.

Task 5C: Use:

Use this protocol for the following situations:

A sampled resident who flagged for the sentinel event of dehydration on the Resident Level Summary;

A sampled resident who has one or more QI conditions identified on the Resident Level Summary, such as:

#11 - Fecal impaction;

#12 - Urinary tract infections;

#13 - Weight loss;

#14 - Tube feeding;

#17 - Decline in ADLs;

#24 - Pressure Ulcer

A sampled resident who was discovered to have any of the following risk factors: vomiting/diarrhea resulting in fluid loss, elevated temperatures and/or infectious processes, dependence on staff for the provision of fluid intake, use of medications including diuretics, laxatives, and cardiovascular agents, renal disease, dysphasia, a history of refusing fluids, limited fluid intake or lacking the sensation of thirst.

Procedures:

Observations/interviews conducted as part of this procedure should be recorded on the Forms CMS-805 and/or the Form CMS-807.

Determine if the resident was assessed to identify risk factors that can lead to dehydration, such as those listed above and also whether there were abnormal laboratory test values which may be an indicator of dehydration.

NOTE: A general guideline for determining baseline daily fluid needs is to multiply the resident's body weight in kilograms (kg) x 30ml (2.2 lbs = 1 kg), except for residents with renal or cardiac distress, or other restrictions based on physician orders. An excess of fluids can be detrimental for these residents.

Determine if an interdisciplinary care plan was developed utilizing the clinical conditions and risk factors identified, taking into account the amount of fluid that the resident requires. If the resident is receiving enteral nutritional support, determine if the tube feeding orders included a sufficient amount of free water, and whether the water and feeding are being administered in accordance with physician orders?

Observe the care delivery to determine if the interventions identified in the care plan have been implemented as described.

What is the resident's response to the interventions? Does staff provide the necessary fluids as described in the plan? Do the fluids provided contribute to dehydration, e.g., caffeinated beverages, alcohol? Was the correct type of fluid provided with a resident with dysphasia?

Is the resident able to reach, pour and drink fluids without assistance? Is the resident consuming sufficient fluids? If not, is staff providing the fluids according to the care plan?

Is the resident's room temperature (heating mechanism) contributing to dehydration? If so, how is the facility addressing this issue?

If the resident refuses water, are alternative fluids offered that are tolerable to the resident?

Are the resident's beverage preferences identified and honored at meals?

Does staff encourage the resident to drink? Are they aware of the resident's fluid needs? Is staff providing fluids during and between meals?

Determine how the facility monitors to assure that the resident maintains fluid parameters as planned. If the facility is monitoring the intake and output of the resident, review the record to determine if the fluid goals or calculated fluid needs were met consistently.

Review all related information and documentation to look for evidence of identified causes of the condition or problem. This inquiry should include interviews with appropriate facility staff and health care practitioners, who by level of training and knowledge of the resident, should know of, or be able to provide information about the causes of a resident's condition or problem.

NOTE: If a resident is at an end of life stage and has an advance directive, according to State law, (or a decision has been made by the resident's surrogate or representative, in accordance with State law) or the resident has reached an end of life stage in which minimal amounts of fluids are being consumed or intake has ceased, and all appropriate efforts have been made to encourage and provide intake, then dehydration may be an expected outcome and does not constitute noncompliance with the requirement for hydration. Conduct observations to verify that palliative interventions, as described in the plan of care, are being implemented and revised as necessary, to meet the needs/choices of the resident in order to maintain the resident's comfort and quality of life. If the facility has failed to provide the palliative care, cite noncompliance with 42 CFR 483.25, F309, Quality of Care.

Determine if the care plan is evaluated and revised based on the response, outcomes, and needs of the resident.

Task 6: Determination of Compliance:

Compliance with 42 CFR 483.25(j), F327, Hydration:

For this resident, the facility is compliant with this requirement to maintain proper hydration if they properly assessed, care planned, implemented the care plan, evaluated the resident outcome, and revised the care plan as needed. If not, cite at F327.

Compliance with 42 CFR 483.20(b)(1) & (2), F272, Comprehensive Assessments:

For this resident in the area of hydration, the facility is compliant with this requirement if they assessed factors that put the resident at risk for dehydration, whether chronic or acute. If not, cite at F272.

Compliance with 42 CFR 483.20(k)(1), F279, Comprehensive Care Plans:

For this resident in the area of hydration, the facility is compliant with this requirement if they developed a care plan that includes measurable objectives and timetables to meet the resident's needs as identified in the resident's assessment. If not, cite at F279.

Compliance with 42 CFR 483.20(k)(3)(ii), F 282, Provision of care in accordance with the care plan:

For this resident in the area of hydration, the facility is compliant with this requirement if qualified persons implemented the resident's care plan. If not, cite at F282.

EXCERPTS FROM SOM APPENDIX P – TASK 6 – Information Analysis for Deficiency Determination
(For complete text refer to SOM Appendix P)

A. General Objectives

The objectives of information analysis for deficiency determination are:

To review and analyze all information collected and to determine whether or not the facility has failed to meet one or more of the regulatory requirements;

C. Decision-Making Process

Each member of the team should review his/her worksheets to identify concerns and specific evidence relating to requirements that the facility has potentially failed to meet. In order to identify the facility's deficient practices and to enable collating and evaluating the evidence, worksheets should reflect the source of the evidence and should summarize the concerns on relevant data tags.

In order to ensure that no requirements are missed, proceed through the requirements sequentially as they appear in the interpretive guidelines, preferably section by section. Findings/evidence within each section should be shared by each team member during this discussion. Consider all aspects of the requirements within the tag/section being discussed and evaluate how the information gathered relates to the specifics of the regulatory language and to the facility's performance in each requirement. The team should come to consensus on each requirement for which problems have been raised by any member. If no problems are identified for a particular tag number during the information gathering process, then no deficiency exists for that tag number.

D. Deficiency Criteria

To determine if a deficiency exists, use the following definitions and guidance:

A "deficiency" is defined as a facility's failure to meet a participation requirement specified in the Social Security Act or in Part 483, Subpart B (i.e., 42 CFR 483.5 - 42 CFR 483.75).

To help determine if a deficiency exists, look at the language of the requirement. Some requirements need to be met for each resident. Any violation of these requirements, even for one resident, is a deficiency.

Other requirements focus on facility systems.

Certain facility systems requirements must be met in an absolute sense, e.g., a facility must have an RN on duty 7 days a week unless it has received a waiver. Other facility system requirements are best evaluated comprehensively, rather than in terms of a single incident. In evaluating these requirements the team will examine both the individual parts of the system, e.g., the adequacy of the infection control protocol, the adequacy of facility policy on hand washing, as well as the actual implementation of that system.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-22

DATE: March 10, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes and Home Health Agencies** - Updated Facility Computer Specifications

Letter Summary

- New architecture structure and software requires new minimum system requirements for access to the Quality Improvement and Evaluation System (QIES).
- Nursing homes (NHs) and home health agencies (HHAs) in your states should meet the new minimum system requirements listed in this memo by December 31, 2005.

Need for Facilities to Upgrade their Personal Computers (PCs)

The Quality Net (QNet) is in the process of complying with the Centers for Medicare & Medicaid Services' (CMS') mandated 3-tiered architecture structure and the use of new QNet approved reporting software. The new architecture and software require new minimum system requirements (outlined in Chart 1 below) for users to access the QIES-to-Success Web site.

CMS is scheduled to transition to this new reporting software in January 2006. In addition, much of the software that supports the submission of patient assessments and facility reporting - for example, the NH quality indicator (QI) and HHA outcome (OBQI) reports, and the submission and error reports – will be upgraded to current software versions. As CMS proceeds with plans to perform these needed upgrades to the reporting software, we find that many facilities have very old computer equipment.

Nearly 15,000 NHs responded to a CMS survey about their computer configuration. The survey findings show that about 1/3 of the NH computers are too old to support the new versions of reporting software. Many NHs have not upgraded their computers since the 1998 MDS submission requirements.

The new reporting software will also affect HHAs. Although they weren't surveyed, it is likely there are a large number of HHAs that also have older computers.

Chart 1 below shows the minimum system requirements that are needed in NHs and HHAs to support the reporting upgrades CMS plans to deploy in January 2006. We are requesting the state survey agencies (SA) inform the NHs and HHAs of the need to ensure their computers meet the minimum system requirements. CMS will post notices on the QIES state system and on the QTSO website. NHs and HHAs will not be able to get their needed reports in the future unless they meet these requirements.

When are upgrades needed?
January 2006 is the targeted timeframe for new reporting software to be installed. NHs and HHAs need their PCs to meet the minimum requirements listed in Chart 1 by December 31, 2005. **Please make sure your providers are made aware of these new system requirements.**

What is the impact to Nursing Homes and Home Health Agencies?

If NHs and HHAs don't have PCs meeting the minimum system requirements, they will not be able to access the upgraded QI/OBQI and the error and submission reports.

CHART 1 - End User **Minimum** PC system requirements:	
CPU:	Pentium 3, 500 MHz
Memory:	256 Mb
Operating System:	Windows 2000 or XP
Hard Drive:	500 Mb free space
Browser:	Internet Explorer v5.5 SP2

Questions about the instructions in this memorandum should be addressed to Lori Anderson at 410-786-6190 or via email at LAnderson1@cms.hhs.gov.

Effective Date: The information in this memorandum should be shared within 30 days of the publication date.

Training: The information contained in this announcement should be shared with the NHs and HHAs in your states, QIES coordinators and survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

DATE: March 10, 2005 Ref: S&C-05-21

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes -** Notification of Imminent Issuance of Appendix PP Revisions, State Operations Manual (SOM), Surveyor Guidance for Incontinence and Catheters

Letter Summary

- Issuance of F315 and F316, Incontinence and Catheters is expected within the next several weeks;
- The new guidance consolidates former Tags F315 and F316 into one Tag, F315.

Background

The Centers for Medicare & Medicaid Services (CMS) has had a project underway to convene expert panels to assist in developing revisions to interpretive guidelines at several key Tags in Appendix PP of the SOM. This ongoing project has now produced the second of our planned Tag revisions, for Incontinence and Catheters, which are currently Tags F315 and F316. In addition, Tags F315 and F316 are being revised into one Tag, which will be F315. The document has gone through public comment and subsequent revision and is now in final clearance for issuance in the very near future. The new guidance contains, in addition to interpretive guidelines, an investigative protocol and specific severity guidance for determination of the correct level of severity of outcome to residents from deficiencies at Tag F315.

Discussion

CMS plans more Tag revisions in fiscal years 2005 and 2006, under the current project. Each Tag is proceeding through expert panel development, public comment, panel review of comments, revisions based on those comments, and then internal clearance. For this reason, each Tag is on its own time schedule for issuance. The next Tag revisions, which are expected to be issued within the next few months, are:

- F501, Medical Director;
- F248 & F249, Activities and Activity Director;

New guidance at Appendix P, Part V, Deficiency Categorization concerning determination of severity for deficiencies having a psychosocial outcome to resident (Psychosocial Outcome Guide).

The issuance of other Tags is planned for later dates. We plan to provide prior notification to you as each product nears final issuance.

For questions on this memorandum, please contact Karen Schoeneman at (410) 786-6855 or e-mail at kschoeneman@cms.hhs.gov.

Effective Date: The revised guidance and consolidation of Tag numbers becomes effective upon issuances as a transmittal on the CMS manuals Web site at http://www.cms.hhs.gov/manuals/transmittals/comm_date_dsc.asp. CMS sends the transmittal to states and CMS Regional Offices when it is placed on the Web site and incorporates the new information into the Web-based SOM

shortly thereafter. Please make sure appropriate staff is informed of these changes within 7 business days of transmittal and implemented no later than 60 days after transmittal.

Training: The information contained in this announcement should be shared with all long term care survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-23

DATE: April 14, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes:** Delay in Effective Date for Revision of Appendix PP, State Operations Manual (SOM), Surveyor Guidance for Incontinence and Catheters

Letter Summary

- This memorandum establishes an effective date for new surveyor guidance for incontinence and catheters of June 27, 2005, to match the ASPEN release date.
- We are providing an advance copy of the final issuance to assist in training surveyors and notifying providers.

Discussion

The Centers for Medicare & Medicaid Services plans to issue the new surveyor guidance in Appendix PP for incontinence and catheters in the near future. Since this new guidance collapses current Tags F315 and F316 into one Tag, which will be F315, it necessitates a revision to ASPEN so that the ASPEN version of the regulatory text at F315 matches what is issued in Appendix PP. Because the next ASPEN update is scheduled for the week of June 21, 2005, we are scheduling the effective date of the change to Appendix PP to match the ASPEN release date.
Therefore, the effective date of the Appendix PP issuance will be June 27, 2005.

We are attaching an advance copy of the final text of the new F315 to assist you in training your surveyors and notifying your providers about the new guidance. Note that the regulatory text that is currently at both F315 and F316 is now listed as regulatory text for the new F315, and that the content of the regulatory text is unchanged.

The new guidance contains Interpretive Guidelines, a new Investigative Protocol, and compliance and severity guidance. For questions on this memorandum, please contact Karen Schoeneman at (410) 786-6855 or e-mail at kschoeneman@cms.hhs.gov.

Effective Date: June 27, 2005

Training: The information contained in this announcement should be shared with all long term care survey staff, their managers and the state/RO training coordinators.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management (G-5)

F315

§483.25(d)(1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and

§483.25(d)(2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

INTENT: (F315) CFR 483.25 (d) (1) and (2) Urinary Incontinence and Catheters

The intent of this requirement is to ensure that:

- Each resident who is incontinent of urine is identified, assessed and provided appropriate treatment and services to achieve or maintain as much normal urinary function as possible;
- An indwelling catheter is not used unless there is valid medical justification;
- An indwelling catheter for which continuing use is not medically justified is discontinued as soon as clinically warranted;
- Services are provided to restore or improve normal bladder function to the extent possible, after the removal of the catheter; and
- A resident, with or without a catheter, receives the appropriate care and services to prevent infections to the extent possible.

DEFINITIONS

Definitions are provided to clarify clinical terms related to evaluation and treatment of urinary incontinence and catheter use.

- "Bacteremia" is the presence of bacteria in the bloodstream.
- "Bacteriuria" is defined as the presence of bacteria in the urine.
- "Urinary Incontinence" is the involuntary loss or leakage of urine. There are several types of urinary incontinence, and the individual resident may experience more than one type at a time. Some of the more common types include:
    - o "Functional Incontinence" refers to loss of urine that occurs in residents whose urinary tract function is sufficiently intact that they should be able to maintain continence, but who cannot remain continent because of external factors (e.g., inability to utilize the toilet facilities in time);
    - o "Mixed Incontinence" is the combination of stress incontinence and urge incontinence;
    - o "Overflow Incontinence" is associated with leakage of small amounts of urine when the bladder has reached its maximum capacity and has become distended;
    - o "Stress Incontinence" (outlet incompetence) is associated with impaired urethral closure (malfunction of the urethral sphincter) which allows small amounts of urine leakage when intra-abdominal pressure on the bladder is increased by sneezing, coughing, laughing, lifting, standing from a sitting position, climbing stairs, etc.;
    - o "Transient Incontinence" refers to temporary episodes of urinary incontinence that are reversible once the cause(s) of the episode(s) is (are) identified and treated; and
    - o "Urge Incontinence" (overactive bladder) is associated with detrusor muscle overactivity (excessive contraction of the smooth muscle in the wall of the urinary bladder resulting in a sudden, strong urge (also known as urgency) to expel moderate to large amounts of urine before the bladder is full).
- "Urinary Retention" is the inability to completely empty the urinary bladder by micturition.
- "Urinary Tract Infection" (UTI) is a clinically detectable condition associated with invasion by disease causing microorganisms of some part of the urinary tract, including the urethra (urethritis), bladder (cystitis), ureters (ureteritis), and/or kidney (pyelonephritis). An infection of the urethra or bladder is classified as a lower tract UTI and infection involving the ureter or kidney is classified as an upper tract UTI.
- "Urosepsis" refers to the systemic inflammatory response to infection (sepsis) that appears to originate from a urinary tract source. It may present with symptoms such as fever, hypotension, reduced urine output, or acute change in mental status.

OVERVIEW

Urinary incontinence is not normal. Although aging affects the urinary tract and increases the potential for urinary incontinence, urinary incontinence is not a normal part of aging. In the younger person, urinary incontinence may result from a single cause. In the older individual, urinary incontinence generally involves psychological, physiological, pharmacological and/or pathological factors or co-morbid conditions (e.g., later stages of dementia, diabetes, prostatectomy, medical conditions involving dysfunction of the central nervous system, urinary tract infections, etc.). Because urinary incontinence is a symptom of a condition and may be reversible, it is important to understand the causes and to address incontinence to the extent possible. If the underlying condition is not reversible, it is important to treat or manage the incontinence to try to reduce complications.

Many older adults are incontinent of urine prior to admission to a nursing home. Urinary incontinence and related loss of independence are prominent reasons for a nursing home admission. Articles[1] and data currently available, including CMS

data (e.g., MDS Active Resident Information Report (Item H1b) at www.cms.hhs.gov/states/mdsreports), indicate that more than 50% of the nursing home population experience some degree of urinary incontinence. Whether the resident is incontinent of urine on admission or develops incontinence after admission, the steps of assessment, monitoring, reviewing, and revising approaches to care (as needed) are essential to managing urinary incontinence and to restoring as much normal bladder function as possible.

Various conditions or situations may aggravate the severity of urinary incontinence in nursing home residents. In addition, urinary incontinence may be associated with changes in skin integrity, skin irritation or breakdown, urinary tract infections, falls and fractures, sleep disturbances, and psychosocial complications including social withdrawal, embarrassment, loss of dignity, feelings of isolation, and interference with participation in activities.

Various factors common to elderly individuals may increase the risk of infection including: underlying diseases (e.g., diabetes mellitus), medications that affect immune responses to infection (e.g., steroids and chemotherapy, history of multiple antibiotic usage), conditions that cause incontinence, and indwelling urinary catheters.

The urinary tract is a common source of bacteremia in nursing home residents. Urinary tract infection (UTI) is one of the most common infections occurring in nursing homes and is often related to an indwelling urinary catheter. Without a valid clinical rationale for an indwelling catheter, its use is not an acceptable approach to manage urinary incontinence. Although UTIs can result from the resident's own flora, they may also be the result of microorganisms transmitted by staff when handling the urinary catheter drainage system and/or providing incontinence care. Hand washing remains one of the most effective infection control tools available.

Resources

It is important for the facility to have in place systems/procedures to assure: assessments are timely and appropriate; interventions are defined, implemented, monitored, and revised as appropriate in accordance with current standards of practice; and changes in condition are recognized, evaluated, reported to the practitioner, and addressed. The medical director and the quality assessment and assurance committee may help the facility evaluate existing strategies for identifying and managing incontinence, catheter
use, and UTIs, and ensure that facility policies and procedures are consistent with current standards of practice.

Research into appropriate practices to prevent, manage, and treat urinary incontinence, urinary catheterization, and UTI continues to evolve. Many recognized clinical resources on the prevention and management of urinary incontinence, infection, and urinary catheterization exist. Some of these resources include:

- The American Medical Directors Association (AMDA) at www.amda.com (Clinical Practice Guidelines: Clinical Practice Guidelines, 1996);
- The Quality Improvement Organizations, Medicare Quality Improvement Community Initiatives at www.medqic.org ;
- The CMS Sharing Innovations in Quality website at www.cms.hhs.gov/medicaid/survey-cert/siqhome.asp ;
- Association for Professionals in Infection Control and Epidemiology (APIC) at www.apic.org;
- Centers for Disease Control at www.cdc.gov ;
- The Annals of Long Term Care publications at www.mmhc.com ;
- American Foundation for Urologic Disease, Inc. at www.afud.org ; and
- The American Geriatrics Society at www.americangeriatrics.org.

NOTE: References to non-CMS sources or sites on the internet are provided as a service and do not constitute or imply endorsement of these organizations or their programs by CMS or the U. S. Department of Health and Human Services. CMS is not responsible for the content of pages found at these sites. URL addresses were current as of the date of this publication.

Resident Choice

In the course of developing and implementing care plan interventions for treatment and services related to achieving the highest practicable level of urinary continence, preventing and treating urinary tract infections, and avoiding the use of indwelling catheters without medical justification, it is important to involve the resident and/or her or his surrogate in care decisions and to consider whether the resident has an advance directive in place.

In order for a resident to exercise his or her right appropriately to make informed choices about care and treatment or to refuse treatment, the facility and the resident (or the resident's legal representative) must discuss the resident's condition, treatment options, expected outcomes, and consequences of refusing treatment. The facility should address the resident's concerns and offer relevant alternatives, if the resident has refused specific treatments. (See Resident Rights 483.10(b)(3) and (4) (F154 and F155).)

Advance Directive. A resident who is at the end of life or in terminal stages of an illness or who has multiple organ system failures may have written directions for his or her treatment goals (or a decision has been made by the resident's surrogate or representative, in accordance with State law).

Although a facility's care must reflect a resident's wishes as expressed in the Directive, in accordance with State law, the

presence of an Advance Directive does not absolve the facility from giving supportive and other pertinent care that is not prohibited by the Advance Directive. The presence of a "Do Not Resuscitate" (DNR) order does not indicate that the resident is declining appropriate treatment and services. It only indicates that the resident should not be resuscitated if respirations and/or cardiac function cease.

If the facility has implemented individualized approaches for end-of-life care in accordance with the resident's wishes, and has implemented appropriate efforts to try to stabilize the resident's condition (or indicated why the condition cannot or should not be stabilized), and has provided care based on the assessed needs of the resident, then the development, continuation, or progression of urinary incontinence; the insertion and prolonged use of an indwelling urinary catheter; the development of infection or skin-related complications from urine or an indwelling catheter may be consistent with regulatory requirements.

URINARY INCONTINENCE

42 CFR 483.25 (d) (2) Urinary Incontinence requires that a resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

Urinary incontinence generally involves a number of transitory or chronic progressive factors that affect the bladder and/or the urethral sphincter. Any condition, medication, or factor that affects lower urinary tract function, bladder capacity, urination, or the ability to toilet can predispose residents to urinary incontinence and may contribute to incomplete bladder emptying.

The first steps toward assuring that a resident receives appropriate treatment and services to restore as much bladder function as possible or to treat and manage the incontinence are to identify the resident already experiencing some level of incontinence or at risk of developing urinary incontinence and to complete an accurate, thorough assessment of factors that may predispose the resident to having urinary incontinence. This is followed by implementing appropriate, individualized interventions that address the incontinence, including the resident's capabilities and underlying factors that can be removed, modified, or stabilized, and by monitoring the effectiveness of the interventions and modifying them, as appropriate. The practitioner, may at his or her option, refer residents
to various practitioners who specialize in diagnosing and treating conditions that affect urinary function.

Assessment

Factors contributing to urinary incontinence sometimes may be resolved after a careful examination and review of history. In addition, for a resident who is incontinent of urine, determining the type of urinary incontinence can allow staff to provide more individualized programming or interventions to enhance the resident's quality of life and functional status. A resident should be evaluated at admission and whenever there is a change in cognition, physical ability, or urinary tract function. This evaluation is to include identification of individuals with reversible and irreversible (e.g., bladder tumors and spinal cord disease) causes of incontinence. If the resident has urinary incontinence that has already been investigated, documented, and determined to be irreversible or not significantly improvable, additional studies may be of limited value, unless there has been advancement in available treatments.

Documentation of assessment information may be found throughout the medical record, such as in an admission assessment, hospital records, history and physical, and the Resident Assessment Instrument (RAI). The location of RAI assessment information is identified on the Resident Assessment Protocol (RAP) summary form. It is important that staff, when completing the comprehensive assessment, consider the following:

- Prior history of urinary incontinence, including onset, duration and characteristics, precipitants of urinary incontinence, associated symptoms (e.g., dysuria, polyuria, hesitancy) and previous treatment and/or management, including the response to the interventions and the occurrence of persistent or recurrent UTI;
- Voiding patterns (such as frequency, volume, nighttime or daytime, quality of stream) and, for those already experiencing urinary incontinence, voiding patterns over several days;
- Medication review, particularly those that might affect continence, such as medications with anticholinergic properties (may cause urinary retention and possible overflow incontinence), sedative/hypnotics (may cause sedation leading to functional incontinence), diuretics (may cause urgency, frequency, overflow incontinence), narcotics, alpha-adrenergic agonists (may cause urinary retention in men) or antagonists (may cause stress incontinence in women) calcium channel blockers (may cause urinary retention);[2]
- Patterns of fluid intake, such as amounts, time of day, alterations and potential complications, such as decreased or increased urine output;
- Use of urinary tract stimulants or irritants (e.g., frequent caffeine intake);[3]
- Pelvic and rectal examination to identify physical features that may directly affect urinary incontinence, such as prolapsed uterus or bladder, prostate enlargement, significant constipation or fecal impaction, use of a urinary catheter, atrophic vaginitis, distended bladder, or bladder spasms;
- Functional and cognitive capabilities that could enhance urinary continence and limitations that could adversely affect continence, such as impaired cognitive function or dementia, impaired immobility, decreased manual dexterity, the need for task segmentation, decreased upper and lower extremity muscle strength, decreased vision, pain with move-

ment;
- Type and frequency of physical assistance necessary to assist the resident to access the toilet, commode, urinal, etc. and the types of prompting needed to encourage urination;
- Pertinent diagnoses such as congestive heart failure, stroke, diabetes mellitus, obesity, and neurological disorders (e.g., Multiple Sclerosis, Parkinson's Disease or tumors that could affect the urinary tract or its function);
- Identification of and/or potential of developing complications such as skin irritation or breakdown;
- Tests or studies indicated to identify the type(s) of urinary incontinence (e.g., post-void residual(s) for residents who have, or are at risk of, urinary retention, results of any urine culture if the resident has clinically significant systemic or urinary symptoms), or evaluations assessing the resident's readiness for bladder rehabilitation programs; and
- Environmental factors and assistive devices that may restrict or facilitate a resident's ability to access the toilet (e.g., grab bars, raised or low toilet seats, inadequate lighting, distance to toilet or bedside commodes, availability of urinals, use of bed rails or restraints, or fear of falling).

Types of Urinary Incontinence. Identifying the nature of the incontinence is a key aspect of the assessment and helps identify the appropriate program/interventions to address incontinence.

- Urge Incontinence is characterized by abrupt urgency, frequency, and nocturia (part of the overactive bladder diagnosis). It may be age-related or have neurological causes (e.g., stroke, diabetes mellitus, Parkinson's Disease, multiple sclerosis) or other causes such as bladder infection, urethral irritation, etc. The resident can feel the need to void, but is unable to inhibit voiding long enough to reach and sit on the commode. It is the most common cause of urinary incontinence in elderly persons.
- Stress Incontinence is the loss of a small amount of urine with physical activity such as coughing, sneezing, laughing, walking stairs or lifting. Urine leakage results from an increase in intra-abdominal pressure on a bladder that is not over distended and is not the result of detrusor contractions. It is the second most common type of urinary incontinence in older women.
- Mixed Incontinence is the combination of urge incontinence and stress incontinence. Many elderly persons (especially women) will experience symptoms of both urge and stress called mixed incontinence.
- Overflow Incontinence occurs when the bladder is distended from urine retention. Symptoms of overflow incontinence may include: weak stream, hesitancy, or intermittency; dysuria; nocturia; frequency; incomplete voiding; frequent or constant dribbling. Urine retention may result from outlet obstruction (e.g., benign prostatic hypertrophy (BPH), prostate cancer, and urethral stricture), hypotonic bladder (detrusor under activity) or both. Hypotonic bladder may be caused by outlet obstruction, impaired or absent contractility of the bladder (neurogenic bladder) or other causes. Neurogenic bladder may also result from neurological conditions such as diabetes mellitus, spinal cord injury, or pelvic nerve damage from surgery or radiation therapy. In overflow incontinence, post void residual (PVR) volume (the amount of urine remaining in the bladder within 5 to 10 minutes following urination) exceeds 200 milliliters (ml). Normal PVR is usually 50 ml. or less. A PVR of 150 to 200 may suggest a need for retesting to determine if this finding is clinically significant. Overflow incontinence may mimic urge or stress incontinence but is less common than either of those.
- Functional Incontinence refers to incontinence that is secondary to factors other than inherently abnormal urinary tract function. It may be related to physical weakness or poor mobility/dexterity (e.g., due to poor eyesight, arthritis, deconditioning, stroke, contracture), cognitive problems (e.g., confusion, dementia, unwillingness to toilet), various medications (e.g., anti-cholinergics, diuretics) or environmental impediments (e.g., excessive distance of the resident from the toilet facilities, poor lighting, low chairs that are difficult to get out of, physical restraints and toilets that are difficult to access). Refer to 42 CFR 483.15(e)(1) for issues regarding unmet environmental needs (e.g., handicap toilet, lighting, assistive devices).

  NOTE: Treating the physiological causes of incontinence, without attending to functional components that may have an impact on the resident's continence, may fail to solve the incontinence problem.
- Transient Incontinence refers to temporary or occasional incontinence that may be related to a variety of causes, for example: delirium, infection, atrophic urethritis or vaginitis, some pharmaceuticals (such as sedatives/hypnotics, diuretics, anticholinergic agents), increased urine production, restricted mobility or fecal impaction. The incontinence is transient because it is related to a potentially improvable or reversible cause.

Interventions

It is important that the facility follow the care process (accurate assessment, care planning, consistent implementation and monitoring of the care plan with evaluation of the effectiveness of the interventions, and revision, as appropriate). Recording and evaluating specific information (such as frequency and times of incontinence and toileting and response to specific interventions) is important for determining progress, changes, or decline.

A number of factors may contribute to the decline or lack of improvement in urinary continence, for example: underlying

medical conditions, an inaccurate assessment of the resident's type of incontinence (or lack of knowledge about the resident's voiding patterns) may contribute to inappropriate interventions or unnecessary use of an indwelling catheter. Facility practices that may promote achieving the highest practicable level of functioning, may prevent or minimize a decline or lack of improvement in degree of continence include providing treatment and services to address factors that are potentially modifiable, such as:

- Managing pain and/or providing adaptive equipment to improve function for residents suffering from arthritis, contractures, neurological impairments, etc;
- Removing or improving environmental impediments that affect the resident's level of continence (e.g., improved lighting, use of a bedside commode or reducing the distance to the toilet);
- Treating underlying conditions that have a potentially negative impact on the degree of continence (e.g., delirium causing urinary incontinence related to acute confusion);
- Possibly adjusting medications affecting continence (e.g., medication cessation, dose reduction, selection of an alternate medication, change in time of administration); and
- Implementing a fluid and/or bowel management program to meet the assessed needs.

Options for managing urinary incontinence in nursing home residents include primarily behavioral programs and medication therapy. Other measures and supportive devices used in the management of urinary incontinence and/or urinary retention may include intermittent catheterization; pelvic organ support devices (pessaries); the use of incontinence products, garments and an external collection system for men and women; and environmental accommodation and/or modification.

Behavioral Programs. Interventions involving the use of behavioral programs are among the least invasive approaches to address urinary incontinence and have no known adverse complications. Behavior programs involve efforts to modify the resident's behavior and/or environment. Critical aspects of a successful behavioral program include education of the caregiver and the resident, availability of the staff and the consistent implementation of the interventions.

NOTE: It is important for the comprehensive assessment to identify the essential skills the resident must possess to be successful with specific interventions being attempted. These skills include the resident's ability to: comprehend and follow through on education and instructions; identify urinary urge sensation; learn to inhibit or control the urge to void until reaching a toilet; contract the pelvic floor muscle (Kegel exercises) to lessen urgency and/or urinary leakage; and/or respond to prompts to void.[4] Voiding records help detect urinary patterns or intervals between incontinence episodes and facilitate planning care to avoid or reduce the frequency of episodes.

Programs that require the resident's cooperation and motivation in order for learning and practice to occur include the following:

- "Bladder Rehabilitation/Bladder Retraining" is a behavioral technique that requires the resident to resist or inhibit the sensation of urgency (the strong desire to urinate), to postpone or delay voiding, and to urinate according to a timetable rather than to the urge to void. Depending upon the resident's successful ability to control the urge to void, the intervals between voiding may be increased progressively. Bladder training generally consists of education, scheduled voiding with systematic delay of voiding, and positive reinforcement. This program is difficult to implement in cognitively impaired residents and may not be successful in frail, elderly, or dependent residents. The resident who may be appropriate for a bladder rehabilitation (retraining) program is usually fairly independent in activities of daily living, has occasional incontinence, is aware of the need to urinate (void), may wear incontinence products for episodic urine leakage, and has a goal to maintain his/her highest level of continence and decrease urine leakage. Successful bladder retraining usually takes at least several weeks. Residents who are assessed with urge or mixed incontinence and are cognitively intact may be candidates for bladder retraining; and
- "Pelvic Floor Muscle Rehabilitation," also called Kegel and pelvic floor muscle exercise, is performed to strengthen the voluntary periuretheral and perivaginal muscles that contribute to the closing force of the urethra and the support of the pelvic organs. These exercises are helpful in dealing with urge and stress incontinence. Pelvic floor muscle exercises (PFME) strengthen the muscular components of urethral supports and are the cornerstone of noninvasive treatment of stress urinary incontinence. PFME requires residents who are able and willing to participate and the implementation of careful instructions and monitoring provided by the facility. Poor resident adherence to the exercises may occur even with close monitoring.

Programs that are dependent on staff involvement and assistance, as opposed to resident function, include the following:

- "Prompted Voiding" is a behavioral technique appropriate for use with dependent or more cognitively impaired residents. Prompted voiding techniques have been shown to reduce urinary incontinence episodes up to 40% for elderly incontinent nursing home residents, regardless of their type of urinary incontinence or cognitive deficit—provided that they at least are able to say their name or reliably point to one of two objects.[5] Prompted voiding has three components: regular monitoring with encouragement to report continence status; prompting to toilet on a scheduled basis; and praise and positive feedback when the resident is continent and attempts to toilet. These methods require training,

motivation and continued effort by the resident and caregivers to ensure continued success. Prompted voiding focuses on teaching the resident, who is incontinent, to recognize bladder fullness or the need to void, to ask for help, or to respond when prompted to toilet.

Residents who are assessed with urge or mixed incontinence and are cognitively impaired may be candidates for prompted voiding. As the resident's cognition changes, the facility should consider other factors, such as mobility, when deciding to conduct a voiding trial to determine feasibility of an ongoing toileting program; and

- "Habit Training/Scheduled Voiding" is a behavioral technique that calls for scheduled toileting at regular intervals on a planned basis to match the resident's voiding habits. Unlike bladder retraining, there is no systematic effort to encourage the resident to delay voiding and resist urges. Habit training includes timed voiding with the interval based on the resident's usual voiding schedule or pattern. Scheduled voiding is timed voiding, usually every three to four hours while awake. Residents who cannot self-toilet may be candidates for habit training or scheduled voiding programs.

Intermittent Catheterization. Sterile insertion and removal of a catheter through the urethra every 3-6 hours for bladder drainage may be appropriate for the management of acute or chronic urinary retention. See additional discussion below in "Catheterization".

Medication Therapy. Medications are often used to treat specific types of incontinence, including stress incontinence and those categories associated with an overactive bladder, which may involve symptoms including urge incontinence, urinary urgency, frequency and nocturia. The current literature identifies classifications and names of medications used for various types of incontinence. When using medications, potentially problematic anticholinergic and other side effects must be recognized. The use of medication therapy to treat urinary incontinence may not be appropriate for some residents because of potential adverse interactions with their other medications or other co-morbid conditions. Therefore, it is important to weigh the risks and benefits before prescribing medications for continence management and to monitor for both effectiveness and side effects. As with all approaches attempting to improve control or management of incontinence, the

education and discussion with the resident (or the resident's surrogate) regarding the benefits and risks of pharmacologic therapies is important.

Pessary. A pessary is an intra-vaginal device used to treat pelvic muscle relaxation or prolapse of pelvic organs. Women whose urine retention or urinary incontinence is exacerbated by bladder or uterine prolapse may benefit from placement of a pessary. Female residents may be admitted to the nursing home with a pessary device. The assessment should note whether the resident has a pessary in place or has had a history of successful pessary use. If a pessary is to be used, it is important to develop a plan of care for ongoing management and for the prevention of and monitoring for complications.

Absorbent Products, Toileting Devices, and External Collection Devices. Absorbent incontinence products include perineal pads or panty liners for slight leakage, undergarments and protective underwear for moderate to heavy leakage, guards and drip collection pouches for men, and products (called adult briefs) for moderate or heavy loss. Absorbent products can be a useful, rational way to manage incontinence; however, every absorbent product has a saturation point. Factors contributing to the selection of the type of product to be used should include the severity of incontinence, gender, fit, and ease of use.

Advantages of using absorbent products to manage urinary incontinence include the ability to contain urine (some may wick the urine away from the skin), provide protection for clothing, and preserve the resident's dignity and comfort.

NOTE: Although many residents have used absorbent products prior to admission to the nursing home and the use of absorbent products may be appropriate, absorbent products should not be used as the primary long term approach to continence management until the resident has been appropriately evaluated and other alternative approaches have been considered.

The potential disadvantages of absorbent products are the impact on the resident's dignity, cost, the association with skin breakdown and irritation, and the amount of time needed to check and change them.[6]

It is important that residents using various toileting devices, absorbent products, external collection devices, etc., be checked (and changed as needed) on a schedule based upon the resident's voiding pattern, accepted standards of practice, and the manufacturer's recommendations.

Skin-Related Complications

Skin problems associated with incontinence and moisture can range from irritation to increased risk of skin breakdown. Moisture may make the skin more susceptible to damage from friction and shear during repositioning.

One form of early skin breakdown is maceration or the softening of tissue by soaking. Macerated skin has a white appearance and a very soft, sometimes "soggy" texture.

The persistent exposure of perineal skin to urine and/or feces can irritate the epidermis and can cause severe dermatitis or skin erosion. Skin erosion is the loss of some or all of the epidermis (comparable to a deep chemical peel) leaving a slightly de-

pressed area of skin.

One key to preventing skin breakdown is to keep the perineal skin clean and dry. Research has shown that a soap and water regimen alone may be less effective in preventing skin breakdown compared with moisture barriers and no-rinse incontinence cleansers.[7] Because frequent washing with soap and water can dry the skin, the use of a perineal rinse may be indicated. Moisturizers help preserve the moisture in the skin by either sealing in existing moisture or adding moisture to the skin. Moisturizers include creams, lotions or pastes. However, moisturizers should be used sparingly—if at all—on already macerated or excessively moist skin.

CATHETERIZATION

42 CFR 483.25 (d) (1) Urinary Incontinence requires that a resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary. Some residents are admitted to the facility with indwelling catheters that were placed elsewhere (e.g., during a recent acute hospitalization). The facility is responsible for the assessment of the resident at risk for urinary catheterization and/or the ongoing assessment for the resident who currently has a catheter. This is followed by implementation of appropriate individualized interventions and monitoring for the effectiveness of the interventions.

Assessment

A resident may be admitted to the facility with or without an indwelling urinary catheter (urethral or suprapubic) and may be continent or incontinent of urine. Regardless of the admission status, a comprehensive assessment should address those factors that predispose the resident to the development of urinary incontinence and the use of an indwelling urinary catheter.

An admission evaluation of the resident's medical history and a physical examination helps identify the resident at risk for requiring the use of an indwelling urinary catheter. This evaluation is to include detection of reversible causes of incontinence and identification of individuals with incontinence caused by conditions that may not be reversible, such as bladder tumors and spinal cord diseases. (See the assessment factors discussed under incontinence.) The assessment of continence/incontinence is based upon an interdisciplinary review. The comprehensive assessment should include underlying factors supporting the medical justification for the initiation and continuing need for catheter use, determination of which factors can be modified or reversed (or rationale for why those factors should not be modified), and the development of a plan for removal.

The clinician's decision to use an indwelling catheter in the elderly should be based on valid clinical indicators.

For the resident with an indwelling catheter, the facility's documented assessment and staff knowledge of the resident should include information to support the use of an indwelling catheter. Because of the risk of substantial complications with the use of indwelling urinary catheters, they should be reserved primarily for short-term decompression of acute urinary retention. The assessment should include consideration of the risks and benefits of an indwelling (suprapubic or urethral) catheter; the potential for removal of the catheter; and consideration of complications resulting from the use of an indwelling catheter, such as symptoms of blockage of the catheter with associated bypassing of urine, expulsion of the catheter, pain, discomfort and bleeding.

Intermittent Catheterization

Intermittent catheterization can often manage overflow incontinence effectively. Residents who have new onset incontinence from a transient, hypotonic/atonic bladder (usually seen following indwelling catheterization in the hospital) may benefit from intermittent bladder catheterization until the bladder tone returns (e.g., up to approximately 7 days). A voiding trial and post void residual can help identify when bladder tone has returned.

Indwelling Catheter Use

The facility's documented assessment and staff approach to the resident should be based on evidence to support the use of an indwelling catheter. Appropriate indications for continuing use of an indwelling catheter beyond 14 days may include:[8]

- Urinary retention that cannot be treated or corrected medically or surgically, for which alternative therapy is not feasible, and which is characterized by:
    - o Documented post void residual (PVR) volumes in a range over 200 milliliters (ml);
    - o Inability to manage the retention/incontinence with intermittent catheterization; and
    - o Persistent overflow incontinence, symptomatic infections, and/or renal dysfunction.
- Contamination of Stage III or IV pressure with urine which has impeded healing, despite appropriate personal care for the incontinence; and
- Terminal illness or severe impairment, which makes positioning or clothing changes uncomfortable, or which is associated with intractable pain.

Catheter-Related Complications

An indwelling catheter may be associated with significant complications, including bacteremia, febrile episodes, bladder stones, fistula formation, erosion of the urethra, epididymitis, chronic renal inflammation and pyelonephritis. In addition, in-

dwelling catheters are prone to blockage. Risk factors for catheter blockage include alkaline urine, poor urine flow, proteinuria, and preexisting bladder stones. In the absence of evidence indicating blockage, catheters need not be changed routinely as long as monitoring is adequate. Based on the resident's individualized assessment, the catheter may need to be changed more or less often than every 30 days.

Some residents with indwelling catheters experience persistent leakage around the catheter. Examples of factors that may contribute to leakage include irritation by a large balloon or by catheter materials, excessive catheter diameter, fecal impaction, and improper catheter positioning. Because leakage around the catheter is frequently caused by bladder spasm, leakage should generally not be treated by using increasingly larger catheter sizes, unless medically justified. Current standards indicate that catheterization should be accomplished with the narrowest, softest tube that will serve the purpose of draining the bladder. Additional care practices related to catheterization include:

- Educating the resident or responsible party on the risks and benefits of catheter use;
- Recognizing and assessing for complications and their causes, and maintaining a record of any catheter-related problems;
- Attempts to remove the catheter as soon as possible when no indications exist for its continuing use;
- Monitoring for excessive post void residual, after removing a catheter that was inserted for obstruction or overflow incontinence;
- Keeping the catheter anchored to prevent excessive tension on the catheter, which can lead to urethral tears or dislodging the catheter; and
- Securing the catheter to facilitate flow of urine.

Research has shown that catheterization is an important, potentially modifiable, risk factor for UTI. By the 30th day of catheterization, bacteriuria is nearly universal.[9] The potential for complications can be reduced by:

- Identifying specific clinical indications for the use of an indwelling catheter;
- Assessing whether other treatments and services would appropriately address those conditions; and
- Assessing whether residents are at risk for other possible complications resulting from the continuing use of the catheter, such as obstruction resulting from catheter encrustation, urethral erosion, bladder spasms, hematuria, and leakage around the catheter.

URINARY TRACT INFECTIONS

Catheter-Related Bacteriuria and UTIs/Urosepsis

Most individuals with indwelling catheters for more than 7 days have bacteriuria. Bacteriuria alone in a catheterized individual should not be treated with antibiotics.

A long term indwelling catheter (>2 to 4 weeks) increases the chances of having a symptomatic UTI and urosepsis. The incidence of bacteremia is 40 times greater in individuals with a long term indwelling catheter than in those without one. For suspected UTIs in a catheterized individual, the literature recommends removing the current catheter and inserting a new one and obtaining a urine sample via the newly inserted catheter.[10]

Clinical Evidence That May Suggest UTI

Clinically, an acute deterioration in stable chronic symptoms may indicate an acute infection. Multiple co-existing findings such as fever with hematuria are more likely to be from a urinary source.

No one lab test alone proves that a UTI is present. For example, a positive urine culture will show bacteriuria but that alone is not enough to diagnose a symptomatic UTI. However, several test results in combination with clinical findings can help to identify UTIs such as the presence of pyuria (more than minimal white cells in the urine) on microscopic urinalysis, or a positive urine dipstick test for leukocyte esterase (indicating significant pyuria) or for nitrites (indicating the presence of Enterobacteriaceae). A negative leukocyte esterase or the absence of pyuria strongly suggests that a UTI is not present. A positive leukocyte esterase test alone does not prove that the individual has a UTI.[11]

In someone with nonspecific symptoms such as a change in function or mental status, bacteriuria alone does not necessarily warrant antibiotic treatment. Additional evidence that could confirm a UTI may include hematuria, fever (which could include a variation from the individual's normal or usual temperature range), or evidence of pyuria (either by microscopic examination or by dipstick test). In the absence of fever, hematuria, pyuria, or local urinary tract symptoms, other potential causes of nonspecific general symptoms, such as fluid and electrolyte imbalance or adverse drug reactions, should be considered instead of, or in addition to, a UTI. Although sepsis, including urosepsis, can cause dizziness or falling, there is not clear evidence linking bacteriuria or a localized UTI to an increased fall risk.[12]

Indications to Treat a UTI

Because many residents have chronic bacteriuria, the research-based literature suggests treating only symptomatic UTIs. Symptomatic UTIs are based on the following criteria:[13]

- Residents without a catheter should have at least three of the following signs and symptoms:

- o Fever (increase in temperature of >2 degrees F (1.1 degrees C) or rectal temperature >99.5 degrees F (37.5 degrees C) or single measurement of temperature >100 degrees F (37.8 degrees C));[14]
- o New or increased burning pain on urination, frequency or urgency;
- o New flank or suprapubic pain or tenderness;
- o Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
- o Worsening of mental or functional status (e.g., confusion, decreased appetite, unexplained falls, incontinence of recent onset, lethargy, decreased activity).[15]

• Residents with a catheter should have at least two of the following signs and symptoms:

- o Fever or chills;
- o New flank pain or suprapubic pain or tenderness;
- o Change in character of urine (e.g., new bloody urine, foul smell, or amount of sediment) or as reported by the laboratory (new pyuria or microscopic hematuria); and/or
- o Worsening of mental or functional status. Local findings such as obstruction, leakage, or mucosal trauma (hematuria) may also be present.[16]

Follow-Up of UTIs

The goal of treating a UTI is to alleviate systemic or local symptoms, not to eradicate all bacteria. Therefore, a post-treatment urine culture is not routinely necessary but may be useful in select situations. Continued bacteriuria without residual symptoms does not warrant repeat or continued antibiotic therapy. Recurrent UTIs (2 or more in 6 months) in a noncatheterized individual may warrant additional evaluation (such as a determination of an abnormal post void residual (PVR) urine volume or a referral to a urologist) to rule out structural abnormalities such as enlarged prostate, prolapsed bladder, periurethral abscess, strictures, bladder calculi, polyps and tumors.

Recurrent symptomatic UTIs in a catheterized or noncatheterized individual should lead the facility to check whether perineal hygiene is performed consistently to remove fecal soiling in accordance with accepted practices. Recurrent UTIs in a catheterized individual should lead the facility to look for possible impairment of free urine flow through the catheter, to re-evaluate the techniques being used for perineal hygiene and catheter care, and to reconsider the relative risks and benefits of continuing the use of an indwelling catheter.

Because the major factors (other than an indwelling catheter) that predispose individuals to bacteriuria, including physiological aging changes and chronic comorbid illnesses, cannot be modified readily, the facility should demonstrate that they:

- Employ standard infection control practices in managing catheters and associated drainage system;
- Strive to keep the resident and catheter clean of feces to minimize bacterial migration into the urethra and bladder (e.g., cleaning fecal material away from, rather than towards, the urinary meatus);
- Take measures to maintain free urine flow through any indwelling catheter; and
- Assess for fluid needs and implement a fluid management program (using alternative approaches as needed) based on those assessed needs.

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INVESTIGATIVE PROTOCOL
URINARY CONTINENCE AND CATHETERS

Objectives

- To determine whether the initial insertion or continued use of an indwelling catheter is based upon clinical indication for use of a urinary catheter;
- To determine the adequacy of interventions to prevent, improve and/or manage urinary incontinence; and
- To determine whether appropriate treatment and services have been provided to prevent and/or treat UTIs.

Use

Use this protocol for a sampled resident with an indwelling urinary catheter or for a resident with urinary incontinence.

Procedures

Briefly review the assessment, care plan and orders to identify facility interventions and to guide observations to be made. Staff are expected to assess and provide appropriate care from the day of admission, for residents with urinary incontinence or a condition that may contribute to incontinence or the presence of an indwelling urinary catheter (including newly admitted residents). Corroborate observations by interview and record review.

NOTE: Criteria established in this protocol provide general guidelines and best practices which should be considered when making a determination of compliance, and is not an exhaustive list of mandatory elements.

1. Observation

Observe whether staff consistently implemented care plan interventions across various shifts. During observations of the interventions, note and/or follow up on deviations from the care plan or from current standards of practice, as well as potential negative outcomes.

Observe whether staff make appropriate resident accommodations consistent with the assessment, such as placing the call bell within reach and responding to the call bell, in relation to meeting toileting needs; maintaining a clear pathway and ready access to toilet facilities; providing (where indicated) elevated toilet seats, grab bars, adequate lighting, and assistance needed to use devices such as urinals, bedpans and commodes.

Observe whether assistance has been provided to try to prevent incontinence episodes, such as whether prompting, transfer, and/or stand-by assist to ambulate were provided as required for toileting.

For a resident who is on a program to restore continence or is on a prompted void or scheduled toileting program, note:

- The frequency of breakthrough or transient incontinence;
- How staff respond to the incontinence episodes; and
- Whether care is provided in accord with standards of practice (including infection control practices) and with respect for the resident's dignity.

For a resident who has been determined by clinical assessment to be unable to participate in a program to restore continence or in a scheduled toileting program and who requires care due to incontinence of urine, observe:

- Whether the resident is on a scheduled check and change program; and
- Whether staff check and change in a timely fashion.

For a resident who has experienced an incontinent episode, observe:

- The condition of the pads/sheets/clothing (a delay in providing continence care may be indicated by brown rings/circles,

saturated linens/clothing, odors, etc.);
- The resident's physical condition (such as skin integrity, maceration, erythema, erosion);
- The resident's psychosocial outcomes (such as embarrassment or expressions of humiliation, resignation, about being incontinent);
- Whether staff implemented appropriate hygiene measures (e.g., cleansing, rinsing, drying and applying protective moisture barriers or barrier films as indicated) to try to prevent skin breakdown from prolonged exposure of the skin to urine; and
- Whether the staff response to incontinence episodes and the provision of care are consistent with standards of practice (including infection control practices) and with respect for the resident's dignity.

For a resident with an indwelling catheter, observe the delivery of care to evaluate:
- Whether staff use appropriate infection control practices regarding hand washing, catheter care, tubing, and the collection bag;

- Whether staff recognize and assess potential evidence of symptomatic UTI or other related changes in urine condition (such as onset of bloody urine, cloudiness, or oliguria, if present);
- How staff manage and assess urinary leakage from the point of catheter insertion to the bag, if present;
- If the resident has catheter-related pain, how staff assess and manage the pain; and
- What interventions (such as anchoring the catheter, avoiding excessive tugging on the catheter during transfer and care delivery) are being used to prevent inadvertent catheter removal or tissue injury from dislodging the catheter.

For a resident experiencing incontinence and who has an indwelling or intermittent catheter, observe whether the resident is provided and encouraged to take enough fluids to meet the resident's hydration needs, as reflected in various measures of hydration status (approximately 30ml/kg/day or as indicated based on the resident's clinical condition). For issues regarding hydration, see Guidance at 42 CFR 483.25(j), F327.

2. Interviews

Interview the resident, family or responsible party to the degree possible to identify:
- Their involvement in care plan development including defining the approaches and goals, and whether interventions reflect preferences and choices;
- Their awareness of the existing continence program and how to use devices or equipment;
- If timely assistance is provided as needed for toileting needs, hydration and personal hygiene and if continence care and/or catheter care is provided according to the care plan;
- If the resident comprehends and applies information and instructions to help improve or maintain continence (where cognition permits);
- Presence of urinary tract-related pain, including causes and management;
- If interventions were refused, whether consequences and/or other alternative approaches were presented and discussed; and
- Awareness of any current UTI, history of UTIs, or perineal skin problems.

If the resident has a skin problem that may be related to incontinence, or staff are not following the resident's care plan and continence/catheter care program, interview the nursing assistants to determine if they:

- Are aware of, and understand, the interventions specific to this resident (such as the bladder or bowel restorative/management programs);
- Have been trained and know how to handle catheters, tubing and drainage bags and other devices used during the provision of care; and
- Know what, when, and to whom to report changes in status regarding bowel and bladder function, hydration status, urine characteristics, and complaints of urinary-related symptoms.

3. Record Review

Assessment and Evaluation. Review the RAI, the history and physical, and other information such as physician orders, progress notes, nurses' notes, pharmacist reports, lab reports and any flow sheets or forms the facility uses to document the resident's voiding history, including the assessment of the resident's overall condition, risk factors and information about the resident's continence status, rationale for using a catheter, environmental factors related to continence programs, and the resident's responses to catheter/continence services. Request staff assistance, if the information is not readily available.

Determine if the facility assessment is consistent with or corroborated by documentation within the record and comprehensively reflects the status of the resident for:

- Patterns of incontinent episodes, daily voiding patterns or prior routines;
- Fluid intake and hydration status;
- Risks or conditions that may affect urinary continence;
- Use of medications that may affect continence and impaired continence that could reflect adverse drug reactions;
- Type of incontinence (stress, urge, overflow, mixed, functional, or transient incontinence) and contributing factors;
- Environmental factors that might facilitate or impede the ability to maintain bladder continence, such as access to the toilet, call bell, type of clothing and/or continence products, ambulation devices (walkers, canes), use of restraints, side rails;
- Type and frequency of physical assistance necessary to facilitate toileting;
- Clinical rationale for use of an indwelling catheter;
- Alternatives to extended use of an indwelling catheter (if possible); and
- Evaluation of factors possibly contributing to chronically recurring or persistent UTIs.

Care Plan. If the care plan refers to a specific facility treatment protocol that contains details of the treatment regimen, the protocol must be available to the direct care staff, so that they may be familiar with it and use it. The care plan should clarify any significant deviations from such a protocol for a specific resident. If care plan interventions that address aspects of continence and skin care related to incontinence are integrated within the overall care plan, the interventions do not need to be repeated in a separate continence care plan.

Review the care plan to determine if the plan is based upon the goals, needs and strengths specific to the resident and reflects the comprehensive assessment. Determine if the plan:

- Identifies quantifiable, measurable objectives with time frames to be able to assess whether the objectives have been met;
- Identifies interventions specific enough to guide the provision of services and treatment (e.g., toilet within an hour prior to each meal and within 30 minutes after meals, or check for episodes of incontinence within 30 minutes after each meal or specific times based upon the assessment of voiding patterns);
- Is based upon resident choices and preferences;
- Promotes maintenance of resident dignity;
- Addresses potential psychosocial complications of incontinence or catheterization such as social withdrawal, embarrassment, humiliation, isolation, resignation;
- Includes a component to inform the resident and representative about the risks and benefits of catheter use, on continence management approaches, medications selected, etc.;
- Addresses measures to promote sufficient fluid intake, including alternatives such as food substitutes that have a high liquid content, if there is reduced fluid intake;
- Defines interventions to prevent skin breakdown from prolonged exposure to urine and stool;
- Identifies and addresses the potential impact on continence of medication and urinary tract stimulants or irritants (e.g., caffeine) in foods and beverages;
- Identifies approaches to minimize risk of infection (personal hygiene measures and catheter/tubing/bag care); and
- Defines environmental approaches and devices needed to promote independence in toileting, to maintain continence, and to maximize independent functioning.

For the resident who is not on a scheduled toileting program or a program to restore normal bladder function to the extent possible, determine if the care plan provides specific approaches for a check and change program.

For the resident who is on a scheduled toileting or restorative program (e.g., retraining, habit training, scheduled voiding, prompted voiding, toileting devices), determine whether the care plan:

- Identifies the type of urinary incontinence and bases the program on the resident's voiding/elimination patterns; and
- Has been developed by considering the resident's medical/health condition, cognitive and functional ability to participate in a relevant continence program, and needed assistance.

For the resident with a catheter, determine whether the care plan:

- Defines the catheter, tubing and bag care, including indications, according to facility protocol, for changing the catheter, tubing or bag;
- Provides for assessment and removal of the indwelling catheter when no longer needed; and
- Establishes interventions to minimize catheter-related injury, pain, encrustation, excessive urethral tension, accidental removal, or obstruction of urine outflow.

Care Plan Revision. Determine if the resident's condition and effectiveness of the care plan interventions have been monitored and care plan revisions were made (or justifications for continuing the existing plan) based upon the following:

- The outcome and/or effects of goals and interventions;
- A decline or lack of improvement in continence status;
- Complications associated with catheter usage;
- Resident failure to comply with a continence program and alternative approaches that were offered to try to maintain or improve continence, including counseling regarding the potential consequences of not following the program;
- Change in condition, ability to make decisions, cognition, medications, behavioral symptoms or visual problems;
- Input by the resident and/or the responsible person; and
- An evaluation of the resident's level of participation in, and response to, the continence program.

4. Interviews with Health Care Practitioners and Professionals

If inconsistencies in care or potential negative outcomes have been identified, or care is not in accord with standards of practice, interview the nurse responsible for coordinating or overseeing the resident's care. Determine:

- How the staff monitor implementation of the care plan, changes in continence, skin condition, and the status of UTIs;
- If the resident resists toileting, how staff have been taught to respond;
- Types of interventions that have been attempted to promote continence (i.e., special clothing, devices, types and frequency of assistance, change in toileting schedule, environmental modifications);
- If the resident is not on a restorative program, how it was determined that the resident could not benefit from interventions such as a scheduled toileting program;
- For the resident on a program of toileting, whether the nursing staff can identify the programming applicable to the resident, and:
    - o The type of incontinence;
    - o The interventions to address that specific type;
    - o How it is determined that the schedule and program is effective (i.e., how continence is maintained or if there has been a decline or improvement in continence, how the program is revised to address the changes); and
    - o Whether the resident has any physical or cognitive limitations that influence potential improvement of his/her continence;
- For residents with urinary catheters, whether the nursing staff:
    - o Can provide appropriate justification for the use of the catheter;
    - o Can identify previous attempts made (and the results of the attempts) to remove a catheter; and
    - o Can identify a history of UTIs (if present), and interventions to try to prevent recurrence.

If the interventions defined or care provided do not appear to be consistent with recognized standards of practice, interview one or more health care practitioners and professionals as necessary (e.g., physician, charge nurse, director of nursing) who, by virtue of training and knowledge of the resident, should be able to provide information about the causes, treatment and evaluation of the resident's condition or problem. Depending on the issue, ask about:

- How it was determined that the chosen interventions were appropriate;
- Risks identified for which there were no interventions;
- Changes in condition that may justify additional or different interventions; or how they validated the effectiveness of current interventions; and
- How they monitor the approaches to continence programs (e.g., policies/procedures, staffing requirements, how staff identify problems, assess the toileting pattern of the resident, develop and implement continence-related action plans, how staff monitor and evaluate resident's responses, etc.).

If the attending physician is unavailable, interview the medical director, as appropriate.

DETERMINATION OF COMPLIANCE (Task 6, Appendix P)

Synopsis of regulation (F315)

The urinary incontinence requirement has three aspects. The first aspect requires that a resident who does not have an indwelling urinary catheter does not have one inserted unless the resident's clinical condition demonstrates that it was necessary. The second aspect requires the facility to provide appropriate treatment and services to prevent urinary tract infections; and the third is that the facility attempt to assist the resident to restore as much normal bladder function as possible.

Criteria for Compliance

- Compliance with 42 CFR 483.25(d)(1) and (2), F315, Urinary Incontinence
    - o For a resident who was admitted with an indwelling urinary catheter or who had one placed after admission, the facility is in compliance with this requirement, if staff have:

- Recognized and assessed factors affecting the resident's urinary function and identified the medical justification for the use of an indwelling urinary catheter;

- Defined and implemented pertinent interventions to try to minimize complications from an indwelling urinary catheter, and to remove it if clinically indicated, consistent with resident conditions, goals, and recognized standards of practice;
- Monitored and evaluated the resident's response to interventions; and
- Revised the approaches as appropriate.

If not, the use of an indwelling urinary catheter is not medically justified, and/or the ongoing treatment and services for catheter care were not provided consistent with the resident's needs. Cite F315.

o For a resident who is incontinent of urine, the facility is in compliance with this requirement if they:
- Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
- Defined and implemented interventions to address correctable underlying causes of urinary incontinence and to try to minimize the occurrence of symptomatic urinary tract infections in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's response to preventive efforts and treatment interventions; and
- Revised the approaches as appropriate.

If not, the facility is not in compliance with the requirement to assist the resident to maintain or improve the continence status, and/or prevent the decline of the condition of urinary incontinence for the resident. Cite F315.

o For a resident who has or has had a symptomatic urinary tract infection, the facility is in compliance with this requirement if they have:
- Recognized and assessed factors affecting the risk of symptomatic urinary tract infections and impaired urinary function;
- Defined and implemented interventions to try to minimize the occurrence of symptomatic urinary tract infections and to address correctable underlying causes, in accordance with resident needs, goals, and recognized standards of practice;
- Monitored and evaluated the resident's responses to preventive efforts and treatment interventions; and
- Revised the approaches as appropriate.

If not, the development of a symptomatic urinary tract infection, and/or decline of the resident with one, was not consistent with the identified needs of the resident. Cite F315.

Noncompliance for F315

After completing the Investigative Protocol, analyze the data in order to determine whether or not noncompliance with the regulation exists. Noncompliance for F315 may include (but is not limited to) one or more of the following, including failure to:

- Provide care and treatment to prevent incontinence and/or improve urinary continence and restore as much normal bladder function as possible;
- Provide medical justification for the use of a catheter or provide services for a resident with a urinary catheter;
- Assess, prevent (to the extent possible) and treat a symptomatic urinary tract infection (as indicated by the resident's choices, clinical condition and physician treatment plan);
- Accurately or consistently assess a resident's continence status on admission and as indicated thereafter;
- Identify and address risk factors for developing urinary incontinence;
- Implement interventions (such as bladder rehabilitative programs) to try to improve, maintain or prevent decline of urinary incontinence, consistent with the resident's assessed need and current standards of practice;
- Provide clinical justification for developing urinary incontinence or for the failure of existing urinary incontinence to improve;
- Identify and manage symptomatic urinary tract infections, or explain adequately why they could or should not do so;
- Implement approaches to manage an indwelling urinary catheter based upon standards of practice, including infection control procedures;
- Identify and apply relevant policies and procedures to manage urinary incontinence, urinary catheters and/or urinary tract infections;
- Notify the physician of the resident's condition or changes in the resident's continence status or development of symptoms that may represent a symptomatic UTI (in contrast to asymptomatic bacteriuria).

Potential Tags for Additional Investigation

During the investigation of 42 CFR 483.25(d)(1) and (2), the surveyor may have identified concerns related to outcome, process and/or structure requirements. The surveyor should investigate these requirements before determining whether non-compliance may be present. The following are examples of related outcome, process and/or structure requirements that should be considered:

- **42 CFR 483.10(b)(11), F157, Notification of Changes**
  - o Determine if staff notified the physician of significant changes in the resident's continence, catheter usage, or the development, treatment and/or change in symptomatic UTIs; or notified the resident or resident's representative (where one exists) of significant changes as noted above.
- **42 CFR 483.15(a), F241, Dignity**
  - o Determine if staff provide continence care and/or catheter care to the resident in a manner that respects his/her dignity, strives to meet needs in a timely manner, monitors and helps the resident who cannot request assistance, and strives to minimize feelings of embarrassment, humiliation and/or isolation related to impaired continence.
- **42 CFR 483.20(b)(1), F272, Comprehensive Assessments**
  - o Determine if the facility comprehensively assessed the resident's continence status and resident-specific risk factors (including potential causes), and assessed for the use of continence-related devices, including an indwelling catheter.
- **42 CFR 483.20(k), F279, Comprehensive Care Plans**
  - o Determine if the facility developed a care plan (1) that was consistent with the resident's specific conditions, risks, needs, behaviors, and preferences and with current standards of practice and (2) that includes measurable objectives, approximate timetables, specific interventions and/or services needed to prevent or address incontinence, provide catheter care; and to prevent UTIs to the extent possible.
- **42 CFR 483.20(k)(2)(iii), F280, Comprehensive Care Plan Revision**
  - o Determine if the care plan was reviewed and revised periodically, as necessary, related to preventing, managing, or improving incontinence, managing an indwelling urinary catheter, possible discontinuation of an indwelling catheter, and attempted prevention and management of UTIs.
- **42 CFR 483.20(k)(3)(i), F281, Services Provided Meet Professional Standards**
  - o Determine if services and care were provided for urinary incontinence, catheter care and/or symptomatic UTIs in accordance with accepted professional standards.
- **42 CFR 483.25, F309, Quality of Care**
  - o Determine if staff identified and implemented appropriate measures to address any pain related to the use of an indwelling urinary catheter or skin complications such as maceration, and to provide the necessary care and services in accordance with the comprehensive assessment plan of care.
- **42 CFR 483.25 (a)(3) F312, Quality of Care**
  - o Determine if staff identified and implemented appropriate measures to provide good personal hygiene for the resident who cannot perform relevant activities of daily living, and who has been assessed as unable to achieve and/or restore normal bladder function.
- **42 CFR 483.40(a), F385, Physician Supervision**
  - o Determine if the physician has evaluated and addressed, as indicated, medical issues related to preventing or managing urinary incontinence, catheter usage, and symptomatic UTIs.
- **42 CFR 483.65(b)(3), F444, Infection Control: Hand Washing**
  - o Determine if staff wash their hands after providing incontinence care, and before and after providing catheter care.
- **42 CFR 483.75(f), F498, Proficiency of Nurse Aides**
  - o Determine if nurse aides correctly deliver continence and catheter care, including practices to try to minimize skin breakdown, UTIs, catheter-related injuries, and dislodgement.
- **42 CFR 483.30(a), F353, Sufficient Staff**
  - o Determine if the facility had qualified staff in sufficient numbers to provide necessary care and services on a 24-hour basis, based upon the comprehensive assessment and care plan, to prevent, manage and/or improve urinary incontinence where possible.
- **42 CFR 483.75(i)(2), F501, Medical Director**
  - o Determine whether the medical director, in collaboration with the facility and based on current standards of practice, has developed policies and procedures for the prevention and management of urinary incontinence, for catheter care, and for the identification and management of symptomatic urinary tract infections; and whether the medical director interacts, if requested by the facility, with the physician supervising the care of the resident related to the management of urinary incontinence, catheter or infection issues.

V. DEFICIENCY CATEGORIZATION (Part V, Appendix P)

Once the team has completed its investigation, analyzed the data, reviewed the regulatory requirements, and determined that non-compliance exists, the team must determine the severity of each deficiency, based on the resultant effect or potential for harm to the resident.

The key elements for severity determination for F315 are as follows:

1. Presence of harm/negative outcome(s) or potential for negative outcomes because of lack of appropriate treatment and care. Actual or potential harm/negative outcome for F315 may include, but is not limited to:

- Development, recurrence, persistence, or increasing frequency of urinary incontinence, which is not the result of underlying clinical conditions;
- Complications such as urosepsis or urethral injury related to the presence of an indwelling urinary catheter that is not clinically justified;
- Significant changes in psychosocial functioning, such as isolation, withdrawal, or embarrassment, related to the presence of un-assessed or unmanaged urinary incontinence and/or a decline in continence, and/or the use of a urinary catheter without a clinically valid medical justification; and
- Complications such as skin breakdown that are related to the failure to manage urinary incontinence;

2. Degree of harm (actual or potential) related to the noncompliance. Identify how the facility practices caused, resulted in, allowed or contributed to the actual or potential for harm:

- If harm has occurred, determine if the harm is at the level of serious injury, impairment, death, compromise, or discomfort; and
- If harm has not yet occurred, determine the potential for serious injury, impairment, death, or compromise or discomfort to occur to the resident; and

3. The immediacy of correction required. Determine whether the noncompliance requires immediate correction in order to prevent serious injury, harm, impairment, or death to one or more residents.

The survey team must evaluate the harm or potential for harm based upon the following levels of severity for tag F315. First, the team must rule out whether Severity Level 4, Immediate Jeopardy to a resident's health or safety exists by evaluating the deficient practice in relation to immediacy, culpability, and severity. (Follow the guidance in Appendix Q, Immediate Jeopardy.)

Severity Level 4 Considerations: Immediate Jeopardy to Resident Health or Safety

Immediate Jeopardy is a situation in which the facility's noncompliance with one or more requirements of participation:

- Has allowed/caused/resulted in, or is likely to allow/cause /result in serious injury, harm, impairment, or death to a resident; and
- Requires immediate correction, as the facility either created the situation or allowed the situation to continue by failing to implement preventative or corrective measures.

Examples of possible negative outcomes as a result of the facility's deficient practices may include:

- Complications resulting from utilization of urinary appliance(s) without medical justification: As a result of incorrect or unwarranted (i.e., not medically indicated) utilization of a urinary catheter, pessary, etc., the resident experiences injury or trauma (e.g., urethral tear) that requires surgical intervention or repair.
- Extensive failure in multiple areas of incontinence care and/or catheter management: As a result of the facility's noncompliance in multiple areas of continence care or catheter management, the resident developed urosepsis with complications leading to prolonged decline or death.

NOTE: If immediate jeopardy has been ruled out based upon the evidence, then evaluate whether actual harm that is not immediate jeopardy exists at Severity Level 3.

Severity Level 3 Considerations: Actual Harm that is not Immediate Jeopardy

Level 3 indicates noncompliance that results in actual harm, and can include but may not be limited to clinical compromise, decline, or the resident's ability to maintain and/or reach his/her highest practicable well-being.

Examples of avoidable negative outcomes may include, but are not limited to:

- The development of a symptomatic UTI: As a result of the facility's noncompliance, the resident developed a symptomatic UTI, without long term complications, associated with the use of an indwelling catheter for which there was no medical justification.
- The failure to identify, assess and mange urinary retention: As a result of the facility's noncompliance, the resident had persistent overflow incontinence and/or developed recurrent symptomatic UTIs.

- The failure to provide appropriate catheter care: As a result of the facility's noncompliance, the catheter was improperly managed, resulting in catheter-related pain, bleeding, urethral tears or urethral erosion.
- Medically unjustified use of an indwelling catheter with complications: As a result of the facility's noncompliance, a resident who was admitted with a urinary catheter had the catheter remain for an extended period of time without a valid medical justification for its continued use, or a urinary catheter was inserted after the resident was in the facility and used for an extended time without medical justification, during which the resident experienced significant complications such as recurrent symptomatic UTIs.
- Decline or failure to improve continence status: As a result of the facility's failure to assess and/or re-assess the resident's continence status, utilize sufficient staffing to implement continence programs and provide other related services based on the resident's assessed needs, and/or to evaluate the possible adverse effects of medications on continence status, the resident failed to maintain or improve continence status.
- Complications due to urinary incontinence: As a result of the facility's failure to provide care and services to a resident who is incontinent of urine, in accordance with resident need and accepted standards of practice, the resident developed skin maceration and/or erosion or declined to attend or participate in social situations (withdrawal) due to embarrassment or humiliation related to unmanaged urinary incontinence.

NOTE: If Severity Level 3 (actual harm that is not immediate jeopardy) has been ruled out based upon the evidence, then evaluate as to whether Level 2 (no actual harm with the potential for more than minimal harm) exists.

Severity Level 2 Considerations: No Actual Harm with potential for more than minimal harm that is Not Immediate Jeopardy

Level 2 indicates noncompliance that results in a resident outcome of no more than minimal discomfort and/or has the potential to compromise the resident's ability to maintain or reach his or her highest practicable level of well being. The potential exists for greater harm to occur if interventions are not provided.

Examples of potentially avoidable negative outcomes may include, but are not limited to:

- Medically unjustified use of an indwelling catheter: As a result of the facility's noncompliance, the resident has the potential for experiencing complications, such as symptomatic UTIs, bladder stones, pain, etc.
- Complications associated with inadequate care and services for an indwelling catheter: As a result of the facility's noncompliance, the resident has developed potentially preventable non-life-threatening problems related to the catheter, such as leaking of urine due to blockage of urine outflow, with or without skin maceration and/or dermatitis.
- Potential for decline or complications: As a result of the facility's failure to consistently implement a scheduled voiding program defined in accordance with the assessed needs, the resident experiences repeated episodes of incontinence but has not demonstrated a decline or developed complications.

Severity Level 1: No actual harm with potential for minimal harm

The failures of the facility to provide appropriate care and services to improve continence, manage indwelling catheters, and minimize negative outcome places residents at risk for more than minimal harm. Therefore, Severity Level 1 does not apply for this regulatory requirement.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Ref: S&C-05-24

DATE: April 14, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes** - Changes to Staffing Data on the Nursing Home Compare Web Site

Letter Summary

- The purpose of this memorandum is to give the State Survey Agencies (SAs) advance notice of coming refinements to Nursing Home Compare and to notify them of CMS' expectations.
- To further improve the accuracy of staffing data reported on NHC, we are implementing new edits.
- These edits may increase the number of nursing homes that will not have any data displayed or that have their reported staffing data altered.
- CMS is distributing a list of nursing homes to each state that will have deleted staffing data using the new, back-end edits and asking each SA to review its data entry of relevant fields and to seek documentation, if necessary, of the nursing home's claimed staffing level.

The Centers for Medicare & Medicaid Services (CMS) is striving to make further improvements in the accuracy and comprehensiveness of staffing information available on the Nursing Home Compare (NHC) Web site. This information is essential in helping consumers make informed choices about nursing homes. To this end, CMS is implementing a number of changes to the display of staffing information on NHC. Although these changes will, on average, improve the accuracy of the staffing information, the immediate consequence may be that there will be some facilities whose staffing information will be either temporarily excluded from NHC or whose reported staffing ratios will be somewhat altered. Most facilities' staffing information will remain unchanged.

Background

The Department of Health and Human Services has recognized the importance of improving nurse staffing levels and making more accurate and comprehensive staffing information available on NHC to inform consumer choice of nursing homes. The Institute of Medicine (IOM) and the National Quality Forum (NQF) have also recommended improvements to the current reporting of nursing home staffing.

The limitations of staffing data on NHC, derived from the Online Survey, Certification and Reporting (OSCAR) system that was not originally designed for this use, have been widely known for some time. CMS has identified a number of short-term, interim steps for improving the current OSCAR system for reporting nursing home staffing.

Edits

The first interim step is to implement a set of exclusion rules for suspect data. These exclusion rules examine staffing ratios. If staffing ratios for any facility fall above or below certain thresholds or exhibit a very rare configuration, the data are viewed as suspect and will be temporarily excluded from NHC until they are corrected or confirmed. CMS derived these thresholds from comparisons to other independent data sources that are known to be more accurate than OSCAR. These other data sources include Medicaid cost reports, payroll data, and prior CMS staff time studies. Attached is a detailed description of how CMS is implementin g the edits.

Implementing the Edits

Before the edits are implemented, CMS will send each SA a list of all the nursing homes in the state for which staffing data would be excluded when the edits are invoked. We understand that it could take some time for the SA to either correct or confirm the already submitted data; therefore, we are allowing a period of two months before the actual edits are implemented. Subsequent monthly changes to NHC will only involve new surveys and corrections of past surveys that are received monthly by CMS.

Specific Steps and Timeframe for Implementing the Back-end Edits

Beginning in late April, 2005, each SA will receive a list of facilities whose staffing data would be excluded by the CMS edits. The listing will be accompanied by each excluded nursing home's staffing, bed count, and resident census information that were keyed into the OSCAR system. This information will need to be confirmed or corrected. **The sole affirmation that the prior information is correct will not be sufficient to change its status; some new information will be required.**

The SA should first check to see that the fields referring to staffing (CMS-671, F38-F45), resident count (CMS-672, F78), Medicare/Medicaid and hospital status (CMS-671, F9-F10), bed counts (CMS-1539, L17 and L18), have been inputted correctly from the hardcopy CMS-671 and CMS-672 forms submitted by the provider. Any identified input errors should be corrected and the data resubmitted.

If there are no input errors, the forms should be returned (mailed/faxed) to the provider and the provider asked either to confirm or correct the fields noted in #2 above. A small proportion of nursing homes report more total beds than certified beds. For these facilities, one possible reason that a nursing home may have its staffing excluded by the edits is that they reported staffing for the entire facility, but the resident count was reported for only the certified beds. For these particular nursing homes, the provider should correct the form by reporting the total number of residents who potentially receive nursing services from the staff reported on the CMS-671. The provider should correct the forms and return them to the SA. The SA then should resubmit the corrected data. If the provider cannot check the submitted data because the records for the prior survey period are not easily accessible, CMS will continue to exclude display of the provider's staffing data until the provider's next standard survey.

If there is only a handful of nursing homes that reach the point of submitting documentation and/or an explanation, CMS may consider putting their staffing information on NHC on a case-by-case basis. If more than a handful, CMS will develop a procedure for this situation.

Staffing levels have emerged as potentially the most important and visible reflection of potential nursing home quality. As such, we believe it imperative to improve the accuracy of the nurse staffing data that CMS displays on NHC.

Effective Date: Systems to ensure complete follow-up on listing of nursing homes with suspect or missing data should be implemented no later than June 30, 2005.

Training: The information in this announcement should be shared with all survey and certification staff, their managers, and all long-term care providers.

/s/
Thomas E. Hamilton

Attachment

cc: Survey and Certification Regional Office Management (G-5)

Attachment

Imputation of Resident Counts

Due to an ambiguity in the OSCAR reporting form CMS-672, about 13 percent of nursing homes report more total beds than certified beds. Unless one assumes that the non-certified beds are empty, the total number of residents is an undercount. This undercount may increase the apparent staffing ratio (nursing hours/residents). The inflated staffing levels results from facilities reporting staffing for all beds, while reporting residents of certified beds.

CMS has attempted to remedy this problem of resident undercount for this minority of nursing homes by invoking an imputation procedure that increases the number of (estimated) residents, thereby lowering the staffing ratio. The edits will have considerable impact on what appears on NHC for some of these facilities. First, about 7 percent of facilities will, as a result of the imputation procedure, fall outside the thresholds and be temporarily excluded until their submitted data are either confirmed or corrected. Second, an additional 8 percent of nursing homes will have altered reported staffing levels on NHC. It is important to note that in some states as many as one-third of all nursing homes may have altered or excluded staffing data. It is likely that many of the excluded providers will demand that their staffing data appear on NHC. Additionally, some portion of nursing homes whose reported staffing on NHC is altered will likely want some response from the SA. In many of these cases, nursing homes will have correctly filled out the CMS forms.

The impact for the SAs and providers will be greatest as CMS first implements the edits and will diminish as providers adjust to the changes and SAs input their surveys for the month.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-25

DATE: April 14, 2005

TO: State Survey Agency Directors
State Fire Authorities

FROM: Director
Survey and Certification Group

SUBJECT: **Nursing Homes** - Adoption of a New Fire Safety Requirement for Long Term Care Facilities (Battery Powered Smoke Detector Installation)

Letter Summary

- This letter announces the publication of a new fire safety requirement for long term care facilities.
- Non-sprinklered facilities are now required to install battery powered smoke detectors in resident rooms and common areas such as dining, activity and other meeting rooms where residents gather.
- Facilities will have one year from the effective date of the regulation to install the required battery operated smoke detectors.

The purpose of this memorandum is to notify states and regional offices (ROs) of the publication on March 25, 2005 in the **Federal Register** (Vol. 70, No. 57, page 15229), of an interim final rule with comment period entitled "Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Amendment." A 60-day comment period, which closes May 24, 2005, is provided for in the rule. We have attached a copy of the regulation to this memorandum.

Regulation Requirement

A recent Government Accountability Office (GAO) report recommended the installation of smoke detectors to provide additional early warning of a fire occurring in a nursing home. This regulation requires, among other items, the installation of battery powered smoke detectors in resident rooms and commons areas in non-sprinklered Long Term Care (LTC) facilities. We have added this change to the Physical Environment requirements at 42 CFR 483.70(a)(7).

All nursing homes that are not fully sprinklered are required to comply with the requirements of this regulation. A fully sprinklered nursing home is one that has all areas sprinklered in accordance with National Fire Protection Association (NFPA) 13 "Standard for the Installation of Sprinkler Systems" without the use of waivers or the Fire Safety Evaluation System (FSES).

The effective date of this regulation is May 24, 2005. We expect to begin surveying facilities for compliance with this requirement on May 24, 2006. This will give providers time to install the required battery powered smoke detectors and to review and make any changes to their facility operating and fire plans.

Installation and Maintenance

The Centers for Medicare & Medicaid Services (CMS) expects that these battery powered smoke detectors will be installed, at a minimum, in all resident sleeping rooms and common areas such as dining rooms, activity rooms, meeting rooms where residents are located on a regular basis, and other areas in the facility where residents may gather together with other residents, visitors, and staff.

Detectors shall be installed in accordance with the manufacturer's recommendations, but at a minimum, one shall be installed in

each resident sleeping room. In larger rooms detectors shall be installed in accordance with the manufacturer's recommendations but not more than 30 feet apart. The detectors shall be tested weekly and batteries changed at least semi-annually, or, if the battery has a longer life in accordance with the manufacture's recommendations.

Additional maintenance may be required such as cleaning on a regular basis, to ensure the detectors operate properly. CMS expects that facilities will keep records of all maintenance, testing and battery changing and have such records available at the time of any inspection.

Facility fire plans may need to be modified and staff trained in response to the alarm from a smoke detector. It is expected that the staff shall respond to an alarm sounding from one of these detectors by activating the facility wide fire alarm system without delay.

Beginning on May 24, 2006 deficiencies concerning the installation and maintenance of these smoke detectors shall be cited on Life Safety Code (LSC) surveys using the LSC Form CMS-2786R at tag K-54 with a Scope/Severity level of D, E, or F depending on the particular situation. Documentation of the smoke detection system installation should be included in the remarks section of the Form CMS-2786R. **A waiver of this requirement cannot be granted due to the negative impact on the health and safety of the residents of the facility.** Emergency plan deficiencies concerning facility response to individual smoke detector activation should be cited at tag K-48 with a Scope/Severity level of D, E, or F depending on the particular situation.

If you have questions concerning this memorandum, please contact James Merrill (James.Merrill@cms.hhs.gov) at (410)786-6998.

Effective Date: All nursing home facilities must comply with the requirements of this rule by May 24, 2006.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers and state fire authorities and their staff.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management

Attachment

Junction, Kentucky northward to its confluence with the Salt River. Otter Creek from Point D (latitude 37°51′31.77″ N; longitude 86°00′03.79″ W) located approximately 3.4 miles north of Vine Grove, Kentucky to Point E (latitude 37°55′21.95″ N; longitude 86°01′47.38″ W) located approximately 2.3 miles southwest of Muldraugh.

(b) *The regulation.* All persons, swimmers, vessels and other craft, except those vessels under the supervision or contract to local military or Army authority, vessels of the United States Coast Guard, and federal, local or state law enforcement vessels, are prohibited from entering the danger zones without permission from the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky or his/her authorized representative.

(c) *Enforcement.* The regulation in this section, promulgated by the United States Army Corps of Engineers, shall be enforced by the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky and/or other persons or agencies as he/she may designate.

Dated: March 16, 2005.

Michael B. White,

Chief, Operations, Directorate of Civil Works.

[FR Doc. 05–5904 Filed 3–24–05; 8:45 am]

BILLING CODE 3710–92–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 460, 482, 483, and 485

[CMS–3145–IFC]

RIN 0938–AN36

Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period adopts the substance of the April 15, 2004 temporary interim amendment (TIA) 00–1 (101), *Alcohol Based Hand Rub Solutions*, an amendment to the 2000 edition of the Life Safety Code, published by the National Fire Protection Association (NFPA). This amendment will allow certain health care facilities to place alcohol-based hand rub dispensers in egress corridors under specified conditions. This interim final rule with comment period also requires that nursing facilities install smoke detectors in resident rooms and public areas if they do not have a sprinkler system installed throughout the facility or a hard-wired smoke detection system in those areas.

DATES: *Effective date:* These regulations are effective on May 24, 2005.

Comments date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 24, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3145–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3145–IFC, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer, (410) 786–6617; James Merrill, (410) 786–6998; or Mayer Zimmerman, (410) 786–6839.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3145–IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–9994.

I. Background

A. Alcohol-Based Hand Rubs (ABHR)

The Life Safety Code (LSC) is a compilation of fire safety requirements for new and existing buildings that is updated and generally published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated these requirements by reference, while providing the opportunity for a Secretarial waiver of a requirement under certain circumstances. The statutory basis for incorporating NFPA's LSC for our providers is under the Secretary's general rulemaking authority at sections 1102 and 1871 of the Social Security Act.

On January 10, 2003, we published a final rule in the **Federal Register**, entitled "Fire Safety Requirements for Certain Health Care Facilities" (68 FR

1374). In that final rule, we adopted the 2000 edition of the LSC provisions governing Medicare and Medicaid health care facilities. The Office of the Federal Register's rules regarding incorporation by reference state that the document so incorporated is the one referred to as it exists on the date of publication of the final rule. Among other things, the 2000 edition of the LSC prohibited the placement of accelerants, including alcohol-based hand rub (ABHR) dispensers, in egress corridors, but allowed their placement in patient rooms and other appropriate areas. We did not receive any public comments contesting this prohibition during the rulemaking process.

[If you choose to comment on issues in this section, please include the caption ''ABHR RESEARCH'' at the beginning of your comments.]

The ABHRs have become an increasingly common infection control method. The issue of infection control has been a concern identified in numerous research studies and reports. The Centers for Disease Control and Prevention (CDC) reports that there are more than 2 million health care acquired infections per year (*http://www.cdc.gov/handhygiene/firesafety/aha_meeting.htm*). Many of the microorganisms that cause these infections are transmitted to patients because health care workers do not wash their hands or do so improperly or inadequately. Improving hand hygiene is an important step towards reducing the number of health care acquired infections. In October 2002, the CDC posted hand hygiene guidelines for health care settings on its website (*http://www.cdc.gov/handhygiene/firesafety/default.htm*). The guidelines clearly recommended the use of ABHRs. The CDC stated that—

- Compared with soap and water hand washing, ABHRs are more effective in reducing bacteria on hands, cause less skin irritation/dermatitis, and save personnel time;
- Use of ABHRs has been associated with improved adherence to recommended hand hygiene practices;
- Adherence is directly tied to access. The highest possible adherence to hand hygiene practice is achieved when ABHR dispensers are in readily accessible locations such as the corridor near the patient room entrance and inside patient rooms; and
- Improved hand hygiene practices have been associated with reduced health care-associated infection rates.

Research from a variety of sources confirms the CDC's research and statements about the usefulness and effectiveness of ABHRs in health care facilities. For example, the study ''Improving adherence to hand hygiene practice: A multidisciplinary approach'' (Pittet D. Emerging Infectious Diseases. 2001 March–April; 7(2):243–40. Review) concludes that, ''[a]lcohol-based hand rub, compared with traditional handwashing with unmedicated soap and water or medicated hand antiseptic agents, may be better because it requires less time, acts faster, and irritates hands less often.''

The same study goes on to state that, ''[t]his method was used in the only program that reported a sustained improvement in hand hygiene compliance with decreased infection rates.'' The relationship between ABHRs and improved adherence to recommended hand hygiene practices is also found in other studies, including ''Availability of an alcohol solution can improve hand disinfection compliance in an intensive care unit'' (Maury E, *et al.* American Journal of Respiratory and Critical Care Medicine, 2000; 162:324–327). This study saw compliance with hand hygiene practice rates rise from 42.4 percent before the introduction of ABHRs to 60.9 percent after the introduction of ABHRs. Each category of health care provider, from nurses to physicians, and even patients increased compliance with hand hygiene practices.

Another study, ''Effectiveness of a hospital-wide programme to improve compliance with hand hygiene'' (Pittet D, Hugonnet S, Harbarth S, *et al.* Lancet 356. 2000; 1307–1312), also demonstrated an increase in compliance with hand hygiene practices that was directly related to the use of ABHRs. In this study, compliance rates rose from 47.6 percent to 66.2 percent over a 3-year period. Handwashing rates remained stable at 30 percent during this period while hand disinfection rates rose from 13.6 percent to 37.0 percent. During this time, the annual amount of ABHR use increased from 3.5L per 1,000 patients to 10.9L per 1,000 patients. The increase in hand disinfection through ABHRs and related increase in compliance with hand hygiene practices are directly tied to the increased availability and use of ABHRs.

An important aspect of getting health care workers and others to use ABHRs is their accessibility. In the study ''Handwashing compliance by health care workers: The impact of introducing an accessible, alcohol-based antiseptic'' (Bischoff WE, *et al.* Archives of Internal Medicine, 2000; 160: 1017–1021), researchers assessed how the accessibility of ABHRs impacted their use. The researchers found that when one ABHR dispenser was available for every four patient beds the adherence rate for hand hygiene was 19 percent before patient contact and 41 percent after patient contact. When one ABHR dispenser was available for each bed, the rates rise to 23 percent before patient contact and 48 percent after patient contact. Increased availability of ABHR dispensers resulted in increased hand hygiene rates.

The relationship between increased availability and increased use is likely the result of several factors. An increase in the number of ABHR dispensers acts as a continuous reminder to workers and others that they need to disinfect their hands. For example, each time an individual approaches a patient area, he or she may see, right next to the door, an ABHR dispenser. The dispenser reminds an individual to disinfect his or her hands. In addition to reminding an individual, the location of ABHR dispensers in obvious and highly visible locations serves as a convenient way to disinfect hands. Rather than repeatedly walking to a sink located in another area, a worker can use the ABHR as he or she enters a patient's room as well as while inside the room. Easy and immediate access to ABHR dispensers is a key element in improving adherence to hand hygiene practices.

Improving hand hygiene has a direct effect on the number of health care acquired infections. Following the introduction of ABHRs in one hospital, there was a reduction in the proportion of methicillin-resistant *S. aureus* infections for each of the quarters of 2000–2001, when ABHRs were utilized, compared with 1999–2000, when ABHRs were not utilized. There was also a 17.4 percent reduction in the incidence of Clostridium difficile-associated disease from 11.5 cases per 1,000 admissions before the introduction of ABHRs to 9.5 cases per 1000 admissions after the introduction of ABHRs (Gopal Rao G, Jeanes A, Osman M, *et al.* Marketing hand hygiene in hospitals: A case study. Journal of Hospital Infection 2002; 50:42–47).

[If you choose to comment on issues in this section, please include the caption ''ABHR SAFETY'' at the beginning of your comments.]

The benefits of using ABHRs have been well demonstrated. However, until a short time ago there were concerns about placing ABHR dispensers in egress corridors. The ABHRs are most commonly found in a gel form contained in a single use disposable bag that is inserted into a wall-mounted dispenser, similar in appearance to wall-mounted hand soap dispensers. The dispenser compresses the bag to

dispense the gel. During normal operation and replacement, the dispenser remains a closed system, meaning that vapors are not released into the atmosphere. In addition, refilling is done using single-use disposable bags rather than large bulk containers. The relatively small quantity of gel in each dispenser combined with the absence of vapor release means that these dispensers, when properly installed and used, pose little fire risk in health care facilities.

In July 2003, the American Hospital Association (AHA), in conjunction with the CDC, held a stakeholder meeting with representatives from more than 20 governmental and non-governmental agencies, including CMS, to discuss the issue of the placement and use of ABHRs. During the meeting, the AHA presented a fire modeling study that was conducted by Gage-Babcock & Associates, Inc. on behalf of the AHA's sister organization, the American Society for Healthcare Engineering (ASHE). This study demonstrated that placing ABHR dispensers in egress corridors is safe, provided that certain conditions are met *(http://www.hospitalconnect.com/ashe/currentevent/alcohol_based_hand_rub/Final_Report_rev1.2_Part_1_2.pdf).*

In February 2004, the ASHE submitted and received approval for temporary interim amendment (TIA) 00–1 (101), *Alcohol-Based Hand Rub Solutions,* to amend the 2003 edition of the LSC. This TIA permitted the placement of ABHR dispensers in egress corridors if certain criteria are met. During a meeting of the NFPA's Standards Council on April 15, 2004, TIA 00–1 (101) was approved for the 2003 edition of the LSC. The TIA was also approved for the 2000 edition of the LSC (the edition CMS adopted). The TIA altered chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC. The change became effective May 5, 2004.

Normally, when the NFPA amends the LSC, it amends the most recently published edition of the code. The most recently published edition is the 2003 edition. However, when the NFPA amended the LSC this time, it retroactively amended the 2000 edition of the LSC in addition to the 2003 edition of the LSC. This is the first time that the NFPA ever retroactively adopted an amendment for an earlier edition of the LSC.

We are adopting the amendment to chapters 18 and 19 of the 2000 edition of the LSC, specifically the changes to chapters 18.3.2.7 and 19.3.2.7. Adopting the amended chapters will allow health care facilities to place ABHR dispensers in egress corridors. We are not adopting the entire revised 2000 edition of the LSC. Anything in the non-amended version of the 2000 edition of the LSC that is contrary to the amended policy will not apply.

Chapters 18 and 19 will apply to hospitals, long-term care facilities, religious non-medical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, intermediate care facilities for the mentally retarded, and critical access hospitals.

Ambulatory surgical centers (ASC) are not covered under chapters 18 or 19 of the LSC; but are rather covered under chapter 21 of the LSC. Many ASCs are interested in installing ABHR dispensers in corridors. However, chapter 21 of the LSC has not been amended thus far to permit the installation of ABHR dispensers in egress corridors in ASCs. We are allowing ASCs to install ABHR dispensers in egress corridors according to the same conditions identified for other health care facilities.

We consider a health care facility to be in compliance with our requirements if the placement of ABHR dispensers meets the specified conditions listed in section II.A of this interim final rule with comment period. The ABHR dispensers will also be required to meet the following criteria that are listed in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC:

- Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m).
- The maximum individual dispenser fluid capacity shall be:

—0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

—0.5 gallons (2.0 liters) for dispensers in suites of rooms.

- The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.
- Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.
- Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code.*
- The dispensers shall not be installed over or directly adjacent to an ignition source.
- In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

After careful and thorough consideration of the numerous studies and recommendations presented above, we believe that placing ABHR dispensers in all appropriate areas, including corridors, is safe and appropriate for patients and providers alike.

B. Smoke Detectors

A recent Government Accountability Office (GAO) report entitled ''Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversight'' (GAO–04–660, July 16, 2004, *http://www.gao.gov/new.items/d04660.pdf)* examined two long-term care facility fires in 2003 that resulted in 31 resident deaths. The report examined Federal fire safety standards and enforcement procedures, as well as results from fire investigations of these two incidents. The report recommended that fire safety standards for unsprinklered facilities be strengthened. It specifically cited requiring smoke detectors in these facilities as one way to strengthen the requirements.

The fires, in Hartford, Connecticut and Nashville, Tennessee, had several things in common. Each fire began in a resident sleeping room at night, neither of those rooms had a smoke detector, and the majority of victims died from smoke inhalation. The lack of smoke detectors in resident rooms, the report concludes, ''* * * may have delayed staff response and activation of the buildings' fire alarms.''

Relying on an effective and timely staff response is a crucial aspect of the current facility fire safety requirements. Long-term care facilities are required by the LSC (chapters 18.7.1.1 and 19.7.1.1) to have an emergency plan that will be implemented in the event of a fire at the facility. As part of this plan, staff members at Medicare-approved facilities are typically expected to do things such as close resident room doors, turn off fans and other air circulation devices, and evacuate residents.

However, battery-operated smoke detectors, a basic fire safety device, are only required by the 2000 edition of the Life Safety Code to be installed in existing non-sprinklered resident rooms when those rooms contain furniture that the resident has brought from his or her home. This was not the case in either fire; therefore, smoke detectors were not in the resident sleeping rooms where the fires started and staff members were not aware of the fires until smoke reached the smoke detectors in the

corridors. This delay inhibited timely staff response and may have contributed to resident deaths.

While resident rooms are the leading area of fire origin, fires can and do originate in other areas. For example, a fire could originate in an unoccupied resident activity room. As with resident sleeping rooms, there is a possibility that no one will be aware of this fire until its smoke spread to a corridor where there are smoke detectors. By this time, smoke may have also begun filtering into other areas of the facility such as resident sleeping rooms and public areas that are occupied, thus harming those residents. In order to alert staff and residents in the earliest stages of a fire, we believe that it is necessary to install smoke detectors in resident sleeping rooms and public areas. For these reasons, we are requiring that long-term care facilities that do not have sprinklers must at least install battery-operated smoke detectors in patient rooms and public areas. We have discussed this issue in detail in section II.B of this interim final rule with comment period.

We are specifically soliciting public comment on the placement of smoke detectors in long-term care facilities. Should detectors also be placed in non-public areas such as storage rooms, closets, and offices?

Facilities that choose to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code,* in patient rooms and public areas within the 1 year phase-in period discussed in section II.B of this interim final rule with comment period will be exempt from this requirement. A hard-wired smoke detector system is a system that is wired to both a facility's electrical and fire alarm systems. The detectors draw their energy from a facility's electrical system and use batteries as back-ups in case of power failure. In addition, the detectors communicate with one another so that an alarm in one room would trigger an alarm in every room. The detectors also communicate with the facility's fire alarm system, thus notifying the fire department of the situation. If a facility chose to install a hard-wired system in resident rooms and public areas, then it will not have to install battery-operated smoke detectors because such a system will exceed the requirements of this interim final rule with comment period. Facilities that have installed sprinkler systems throughout in accordance with NFPA 13, *Automatic Sprinklers,* will also be exempt from the proposed requirement to install smoke detectors, because such a system will exceed this requirement.

C. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. We intend to publish the final rule within the 3-year timeframe established under section 902 of the MMA.

II. Provisions of the Interim Final Rule

A. Alcohol-Based Hand Rubs

[If you choose to comment on issues in this section, please include the caption ''PLACEMENT REQUIREMENTS'' at the beginning of your comments.]

For the reasons specified in the preamble, in sections I.A. and I.B. above, we are modifying the conditions of participation for the following facilities:

—Religious non-medical health care institutions (RNHCI) (new § 403.744(a)(4)).
—Ambulatory Surgical Services (ASC) (new § 416.44(b)(5)).
—Hospices (new § 418.100(d)(6)).
—Programs of all-inclusive care for the elderly (PACE) (new § 460.72(b)(6)).
—Hospitals (new § 482.41(b)(9)).
—Long-term care (LTC) facilities (new § 483.70(a)(6)).
—Intermediate care facilities for the mentally retarded (ICFs/MR) (revised § 483.470(j)(7)).
—Critical access hospitals (CAHs) (new § 485.623(d)(7)).

The numbering that appears above corresponds to the most recent changes to the Life Safety Code regulations, published in the **Federal Register** as a final rule on August 11, 2004.

Specifically, we are adding a new provision that will allow these facilities to place ABHR dispensers in various locations, including egress corridors, if the facilities met the following conditions:

- The use of ABHR dispensers could not conflict with any State or local codes that prohibit or otherwise restrict the placement of ABHR dispensers in health care facilities. Allowing ABHR dispensers to be installed in egress corridors will be a significant lessening of restrictions. States and/or local jurisdictions may choose to retain stricter codes that prohibit or otherwise restrict the installation of ABHR dispensers in health care facilities. Facilities will still be required to comply with those stricter State and local codes. Therefore, facilities could only install ABHR dispensers if the dispensers were also permitted by State and local codes.
- The dispensers were installed in a manner that minimized leaks and spills that could lead to falls. Like soap, ABHRs are very slick. As such, it is more likely for someone to slip and fall on a surface that is covered by an ABHR solution than on a surface that is clean.

The increased risk of falls posed by the presence of leaky or spilled ABHR dispensers might be compounded by the medical conditions of patients or residents. While a healthy individual may fall and only suffer a bruise, a frail individual may suffer a broken hip. It is the specific safety needs of the patient populations found in hospitals and other health care facilities that necessitates the requirement that facilities take extra steps to ensure that ABHR dispensers do not leak or spill.

In addition to any extra steps such as additional hardware installation, facilities should follow all manufacturer maintenance recommendations for ABHR dispensers. Regular maintenance of dispensers in accordance with the directions of the manufacturer is a crucial step towards ensuring that the dispensers do not leak or spill.

- The dispensers were installed in a manner that adequately protected against access by vulnerable populations, such as residents in psychiatric units. There are certain patient or resident populations, such as residents of dementia wards, who may misuse ABHR solutions, which are both toxic and flammable. As a toxic substance, ABHR solutions are very dangerous if they are ingested, placed in the eyes, or otherwise misused. As a flammable substance, ABHR solutions could be used to start fires that endanger the lives of patients and destroy property.

Due to disability or disease, some patients are more likely to harm themselves or others by misusing ABHR solutions. In order to avoid any and all dangerous situations, a facility will have to take all appropriate precautions to secure the ABHR dispensers from misuse by these vulnerable populations.

- The dispensers were installed in accordance with chapters 18.3.2.7 and

19.3.2.7 of the 2000 edition of the LSC. The revisions to the chapters were thoroughly examined by the NFPA's fire safety experts and are based on the fire modeling study conducted by Gage-Babcock for the ASHE. As noted above, the study demonstrated that ABHR dispensers installed in egress corridors do not increase the risk of fire if certain conditions, as outlined in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC, are met. The study also showed that if those conditions are not met, there will be an increase in the risk of fire.

B. Smoke Detectors

[If you choose to comment on issues in this section, please include the caption ''LOCATION'' at the beginning of your comments.]

We are requiring in § 483.70(a)(7) that long-term care facilities will, at minimum, be required to install battery-operated smoke detectors in resident sleeping rooms and public areas, unless they have a hard-wired smoke detector system in resident rooms and public areas or a sprinkler system throughout the facility. We are also requiring that facilities that install battery-operated smoke detectors have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Smoke detectors, when properly installed and maintained in resident sleeping rooms and public areas, are a basic, useful and effective fire safety tool.

We believe that at least installing battery-operated smoke detectors will provide earlier warning for facility residents and staff. Fires that originate in these areas will be detected earlier because the detector will be located closer to the fire's origin than if it were only placed in the corridor. Earlier detection, and thus earlier alarm, will allow residents and staff more time to react to the situation and implement the facility's emergency plan. Implementing the emergency plan typically includes notifying the fire department, and this earlier notification will speed the arrival of help. These factors could help to reduce the loss of life in a nursing facility fire.

[If you choose to comment on issues in this section, please include the caption ''MAINTENANCE'' at the beginning of your comments.]

As discussed earlier, a facility will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Detectors require maintenance every 6 months to 1 year in order to ensure that the batteries are operating at optimum power. A detector with a depleted battery provides no protection. Thus, a regular maintenance program for the detectors is crucial to ensuring that residents and staff are indeed protected. Facilities will be expected to add maintenance of smoke detectors to their existing maintenance schedule.

[If you choose to comment on issues in this section, please include the caption ''1 YEAR PHASE-IN'' at the beginning of your comments.]

We are allowing facilities 1 year to comply with this regulation for two reasons. First, allowing facilities an extra year to comply with this regulation will also give interested facilities additional time to purchase and install a hard-wired smoke detector system or a sprinkler system. Purchasing and installing these systems is more complicated than purchasing and installing battery-operated detectors. Therefore, facilities that wanted to exercise this option would be prohibited from doing so if they were required to comply immediately. The 1-year phase-in will give facilities a chance to purchase and install a more advanced fire and smoke protection system than this regulation requires. We are strongly in favor of facilities taking advantage of this extended compliance period to install more advanced fire protection systems than the battery-operated smoke detectors that are required by this regulation.

Second, some facilities might have difficulty obtaining and installing battery-operated smoke detectors within the typical 60-day period from the date of publication of a final rule to the rule's effective date. Therefore, we are allowing facilities to phase-in smoke detectors over a 1-year period from the effective date of a final regulation. Facilities could use this year to purchase and install battery-operated detectors, or they could do so on an abbreviated schedule. We encourage facilities that choose to install battery-operated smoke detectors to do so as quickly as possible in order to increase fire safety. We believe that this phase-in period will give facilities more flexibility in meeting this requirement.

[If you choose to comment on issues in this section, please include the caption ''EXCEPTIONS'' at the beginning of your comments.]

The regulation will have two exceptions, one for facilities that have hard-wired smoke detection systems and one for facilities that have sprinkler systems. Hard-wired smoke detector systems installed in resident rooms and public areas will protect the same areas as the battery-operated detectors. Therefore, having both hard-wired and battery-operated detectors in these areas will be redundant, unnecessary, and overly burdensome. Facilities may still choose to use battery-operated detectors along with hard-wired detectors as an additional layer of fire protection, but we will not require the facilities to do so in this interim final rule with comment period.

Likewise, having both a sprinkler system throughout and battery-operated smoke detectors in resident rooms and public areas will duplicate fire safety efforts.

Sprinklers are considered to be the best way to protect building occupants in fires. Their response time and their ability to extinguish fires before they become a significant hazard will make battery-operated smoke detectors an unnecessary requirement. Facilities may still choose to use detectors as an additional layer of fire protection beyond sprinklers, but they will not be required to do so in this interim final rule with comment period.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that continuing to prohibit the placement of ABHR dispensers in all appropriate areas, including egress corridors, is contrary to the public interest because ABHRs are a safe and effective method for increasing hand hygiene compliance rates, and their use has been shown to help decrease health care-acquired infections. As the studies and recommendations described in section I.A of this document

demonstrate, ABHRs are a safe and effective method for cleansing hands.

Although ABHR dispensers were once considered to be a fire safety risk when placed in egress corridors, they are no longer considered by fire safety experts to pose a significant risk to patient safety. According to the Gage-Babcock study, ABHR dispensers can be safely installed in egress corridors if they meet certain specifications, such as being placed at least 4 feet apart and not being placed over carpet in an unsprinklered smoke compartment. Fire safety experts believe that dispensers of ABHRs, when installed properly in egress corridors, do not decrease fire safety. We agree with this position.

Any fire safety concerns are, we believe, more than offset by the potential for health care facilities to improve their infection control practices. As the availability of ABHRs increases in a facility, so does the rate of hand hygiene compliance. An increase in hand hygiene compliance rates results in a decrease in health care acquired infections. We believe that the public will benefit from more ABHR dispensers being available in more places because the increased availability of ABHR dispensers will likely decrease the number of health care acquired infections, thus improving public health and safety in health care facilities.

We believe that allowing long-term care facilities to continue to care for residents in buildings that have neither sprinklers nor smoke detectors is contrary to the public interest because buildings that do not at least have smoke detectors present a greater risk of death or injury due to fire. In 2003, 31 long-term care facility residents died in two separate fires in buildings that did not have smoke detectors in patient rooms, where both fires started, or in public areas. Smoke detectors are basic and relatively inexpensive fire safety tools that have been proven to be effective at alerting residents and staff to fire, and that have been in use in homes and other buildings across the country for several decades. They provide early warning to occupants and have saved countless lives. Continuing to allow long-term care facilities that care for residents in buildings lacking smoke detectors risks the safety of all residents and staff in these buildings.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have examined the impact of this interim final rule with comment period, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, most entities affected by this interim final rule with comment period are considered small businesses according to the Small Business Administration's size standards, with total revenues of $29 million or less in any 1 year (for details, see 65 FR 69432). Individuals and States are not included in the definition of a small entity. According to CMS statistics, nursing facilities, which we require to install smoke detectors in resident rooms and public areas, earned a total of $89.6 billion in 1999 (*http://www.cms.hhs.gov/statistics/nhe/historical/t7.asp*). According to the National Nursing Home Survey: 1999 Summary (*http://www.cdc.gov/nchs/data/series/sr_13/sr13_152.pdf*), there were 18,000 nursing facilities in operation at that time. An average facility at this time thus had revenue of approximately $4,977,778. A facility with revenue 50 percent below this average still earned $2,488,889. In the first year, this interim final rule with comment period will cost, on average, approximately $9,800 per facility. In the following years, this interim final rule with comment period will cost $2,800 annually for maintenance. This amount will be less than one half of one percent of the total revenue for an average- or below-average-revenue facility. Therefore, we certify that this interim final rule with comment period will not have a significant impact on a substantial number of small entities. We are not considering hospitals or other facilities affected by the alcohol-based hand rub regulation in this regulatory flexibility analysis because we do not require those facilities to take any action. We are requiring that, if those facilities choose to install ABHR dispensers in egress corridors, then they will have to do so in accordance with the regulation.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This interim final rule with comment period will not have a significant impact on small rural hospitals because the interim final rule with comment period will not impose requirements on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This interim final rule with comment period will not have an effect on State, local, or tribal governments, and the private sector costs will not be greater than the $110 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates an interim final rule with comment period (and subsequent final rule) that imposes substantial direct requirement costs on

State and local governments, preempts State law, or otherwise has Federalism implications. This regulation does not have any Federalism implications.

B. Anticipated Effects

1. Alcohol-Based Hand Rubs

This interim final rule with comment period does not require an affected facility to install ABHR dispensers; thus, the facility will not be mandated with a burden associated with this provision of the regulation.

We, however, will require facilities that choose to install ABHR dispensers to do so in accordance with chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA. Facilities will have to install them in accordance with the LSC, and in a way that minimized leaks and spills, and access to the dispensers by vulnerable populations. Installing dispensers according to the specifications of the LSC and this regulation may increase installation costs. Facilities that choose to install dispensers are required by this regulation to take additional steps to minimize dispenser leaks and spills. While this regulation does not require a specific method for minimizing leaks and spills, facilities may decide to install additional hardware to ensure compliance with this regulation. Additional hardware, such as a device below the dispenser to catch drips, could increase purchasing and installation costs. The leak and spill minimization requirement is new, therefore we have no data to estimate the cost of the provision. We believe that any additional costs are small when compared to the costs of caring for a frail patient who fell on a slippery, ABHR covered floor.

In addition, the installation of these dispensers in egress corridors was previously prohibited. The requirements for locating dispensers in other areas will not change. Therefore, a facility will not have to relocate or modify existing dispensers to conform to the specifications.

Facilities that choose to install ABHR dispensers in any area, including corridors and patient rooms, are required by the LSC to store large quantities of ABHR solution in a flammable liquids cabinet. Facilities are required to use these cabinets if they choose to store 5 gallons or more of ABHR solution in a single smoke compartment. This LSC requirement helps ensure that large amounts of ABHR solution do not accelerate health care facility fires.

Most hospitals already have these cabinets to store other alcohol products or flammables, and would therefore not need to purchase a special storage container for ABHR solutions. Other facilities that may choose to install ABHR dispensers are typically smaller than hospitals and would not need to store more than five gallons of ABHR solution in a single smoke compartment. A facility with 20 rooms per smoke compartment will likely install 10 ABHR dispensers, for a total of three gallons of ABHR solution per smoke compartment. That same facility would be permitted to keep an additional two gallons of ABHR solution for refilling in that same compartment without using a flammable liquids cabinet. Therefore, we do not believe that this LSC provision will pose a significant burden to facilities that choose to install ABHR dispensers.

Facilities that choose to install ABHR dispensers may expect to see a decrease in health care acquired infections due to an increase in hand hygiene practices by clinicians and non-clinicians. While we cannot quantify the potential benefit of this decrease in infections, we do know that decreasing infection rates lead to better patient care outcomes and decrease patient care costs.

2. Smoke Detectors

The July 2004 GAO report estimated that 20 to 30 percent of long-term care facilities do not have sprinklers throughout the facility and will therefore be subject to the provisions of this regulation. We do not have information on the number of facilities that have a hard-wired smoke detector system in resident rooms and public areas. For the purposes of our analysis, we estimated that 25 percent of long-term care facilities, or 4,200, will be subject to the provisions of this regulation. We estimate that an average long-term care facility in a building that does not have sprinklers has 100 residents in 50 two-person resident sleeping rooms, and that each room will require one battery-operated smoke detector. We estimated that each average facility will require 20 additional detectors for public areas, for a total of 70 detectors per facility. We estimated that the cost of each smoke detector and its installation will be approximately $100. Therefore, an average facility will expect to pay $7,000 to purchase and install battery-operated smoke detectors in resident sleeping rooms and public areas. The total industry cost for purchasing and installing battery-operated smoke detectors in the specified areas will be $29,400,000.

Following installation of battery-operated smoke detectors in the specified areas, a long-term care facility will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. We estimate that a facility will conduct monthly tests of each detector by activating the test button. This will take approximately 5 minutes per smoke detector per test, or 1 hour per smoke detector per year.

In addition, we estimate that a facility will clean each detector and change its batteries two times per year. This will take 15 minutes per smoke detector per cleaning and replacement, or 30 minutes per smoke detector per year. We estimate that the total annual maintenance time per detector will be one 1.5 hours, for total of 105 hours per average facility.

We estimate that the cost for this provision for an average long-term care facility with 70 smoke detectors, based on a maintenance person earning $20 per hour and $5 for batteries per change, is $2,800. The annual industry total for this maintenance provision will thus be $11,760,000.

The total cost for the first year of this regulation, including purchase, installation and maintenance costs, will be $9,800 per average facility, for a total of $41,160,000 industry wide. The cost for the following years of maintenance will be $2,800 per average facility annually, or $11,760,000 industry wide annually.

C. Alternatives Considered

1. Alcohol-Based Hand Rubs

We considered not adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA, thereby continuing to prohibit the placement of ABHR dispensers in egress corridors. However, continuing this prohibition was not acceptable for two reasons. First, we want to improve hand hygiene practices in order to reduce health-care-acquired infections. Hand hygiene levels increase when the availability of hygiene stations, such as ABHR dispensers, increase. It is helpful to have these stations in areas that are highly visible and easily accessed, as they are in corridors. Therefore, the potential to increase hand hygiene and thus decrease health care acquired infections by placing ABHR dispensers in all appropriate locations warranted this regulation.

Second, continuing to prohibit ABHR dispensers in egress corridors is contrary to our goal of increasing provider flexibility. We believe that, wherever possible, providers should be allowed the flexibility to meet the needs of their patients/residents in the manner they see fit. Providers are aware of the

hazards posed by infections and have developed many methods for addressing those hazards. The ABHR dispensers are one method, and we believe that providers should be allowed to utilize the ABHR dispensers to the fullest extent within the context of patient safety.

We also considered adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC without the additional requirements. However, the chapters do not address several important areas of patient safety, and we believe that not addressing these areas may put patient safety at risk. The NFPA is dedicated to reducing loss of life due to fires. As such, it concerned itself solely with the fire safety implications of installing ABHR dispensers in egress corridors. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address leaks and spills that will result in people slipping and falling, nor did they address the potential for inappropriate use of ABHRs by vulnerable populations such as patients in ICFs/MR or dementia units. Due to disability or illness, these populations require additional protection from substances that are toxic and/or flammable. The ABHRs are both toxic and flammable. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address these non-fire safety issues. Therefore, we believe that it is necessary to add other installation requirements in addition to chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC.

2. Smoke Detectors

We considered not requiring long-term care facilities to install smoke detectors; however, we believe that installation of the smoke detectors will help save lives. The July 2004 GAO report clearly outlined the role that smoke detectors, one of the most basic and effective fire safety devices available, played in the Nashville and Hartford fires. The report also outlined the wider role that detectors can and should play in long-term care facility fire safety. The positive impact of smoke detectors on resident safety, we believe, warrants their installation.

We also considered requiring long-term care facilities to immediately install battery-operated smoke detectors, rather than allowing facilities to phase them in over a 1-year period. We strongly support a facility's choice to install a fire safety system that exceeds the requirements of this regulation. It would have been extremely difficult for facilities that wanted to install hard-wired smoke detector systems or sprinkler systems to complete their tasks in 60 days. The 1-year phase-in period will allow those facilities more time to complete these systems, which would go beyond what we are requiring in this rule.

In addition, requiring facilities to, at a minimum, install battery-operated smoke detectors in 60 days would have posed a significant time and financial burden to facilities. Had we chosen this option, we would have required facilities to purchase and install a fairly large volume of detectors in a fairly short period of time, 60 days. This may have been very difficult for some facilities due to the initial cost of purchasing and installing the detectors. We estimate that it will cost facilities $7,000 to purchase and install battery-operated smoke detectors. There may be facilities that do not have the full amount of funds immediately available, and therefore would not be able to comply with this regulation within the standard 60-day time period. The 1-year phase-in period allows these facilities to distribute the cost over 12 months, for an average monthly cost of $584. Distributing the cost of smoke detectors over a 1-year period ensures that all facilities are able to afford the cost of complying with this rule.

Furthermore, we considered requiring long-term care facilities to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code,* for hard-wired alternating current smoke detector systems. This option would have posed a significant burden to some long-term care facilities because of the cost and time associated with purchasing and installing these devices. Hard-wired detectors must be wired directly into the facility's electrical and fire alarm system. We believe that the costs associated with purchasing this system and the time required to install it would have placed this option out of reach for some nursing facilities.

Therefore, we are requiring only the less expensive and less time consuming battery-operated detector. Facilities may still choose to install a hard-wired smoke detector system, and we encourage them to do so. Installation of such a system in patient rooms and public areas will exempt a facility from installing battery-operated detectors in those areas.

Finally, we considered requiring long-term care facilities that do not have sprinklers to install them. We are aware that the NFPA and long-term care industry are carefully examining this issue in light of the recent fires. We are also aware that installing sprinklers in existing facilities is an expensive proposition. We believe that this issue warrants further examination, and are committed to working with NFPA, the long-term care facility industry, and advocates to develop a consensus position. Any new sprinkler requirements would be discussed in a separate regulatory document and would be published in the **Federal Register**. Facilities may still choose to install a sprinkler system throughout the facility in accordance with NFPA 13. Installation of such a system will exempt a facility from installing battery-operated detectors in patient rooms and public areas. We encourage all facilities to fully explore this option, as it provides the highest level of fire protection currently available.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements

■ For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is amended to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

■ 2. Add new paragraphs (a)(3) and (a)(4) to § 403.744 to read as follows:

§ 403.744 Condition of participation: Life safety from fire.

(a) * * *

(3) [Reserved]

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, the RNHCI may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

■ 4. Add new paragraph (b)(5) to § 416.44 to read as follows:

§ 416.44 Conditions for coverage-Environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

* * * * *

PART 418—HOSPICE CARE

■ 5. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart E—Conditions of Participation: Other Services

■ 6. Add a new paragraph (d)(6) to § 418.100 to read as follows:

§ 418.100 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this

amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 7. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

Subpart E—PACE Administrative Requirements

■ 8. Add a new paragraph (b)(5) to § 460.72 to read as follows:

§ 460.72 Physical environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 9. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

■ 10. Add a new paragraph (b)(9) to § 482.41 to read as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) * * *

(9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 11. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Requirements for Long Term Care Facilities

■ 12. In § 483.70, add new paragraphs (a)(6) and (a)(7) to read as follows:

§ 483.70 Physical environment.

(a) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

(7) A long-term care facility must:

(i) Install battery-operated smoke detectors in resident sleeping rooms and public areas by May 24, 2006.

(ii) Have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors.

(iii) Exception:

(A) The facility has a hard-wired AC smoke detection system in patient rooms and public areas that is installed, tested, and maintained in accordance

with NFPA 72, *National Fire Alarm Code,* for hard-wired AC systems; or

(B) The facility has a sprinkler system throughout that is installed, tested, and maintained in accordance with NFPA 13, *Automatic Sprinklers.*

* * * * *

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

■ 13. Revise paragraph (j)(7) to § 483.470 to read as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *

(7) *Facilities that meet the LSC definition of a health care occupancy.*

(i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 14. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 15. Add a new paragraph (d)(7) to § 485.623 to read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the change.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: September 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 7, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–5919 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI20

Endangered and Threatened Wildlife and Plants; Final Designation of Critical Habitat for Topeka Shiner

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce corrections to the final rule designating critical habitat for the Topeka shiner (*Notropis topeka*), published in the **Federal Register** on July 27, 2004. In the final rule, the map legends incorrectly referred to stream segments as ''proposed'' critical habitat rather than ''designated'' critical habitat, and six transcription errors were included in legal descriptions of critical habitat from Unit 1 (Iowa) and Unit 4 (Minnesota). This document corrects these errors.

DATES: Effective August 26, 2004.

FOR FURTHER INFORMATION CONTACT: Vernon Tabor, Kansas Ecological Services Field Office, 315 Houston Street, Suite E, Manhattan, Kansas 66502 (telephone 785–539–3474; facsimile 785–539–8567). The complete file for this correction document and the rule are available for public inspection, by appointment, during normal business hours at the above address. Copies of the rule, draft economic analysis, and draft environmental assessment are available by writing to the above address or by connecting to the Service

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-30

DATE: June 9, 2005

TO: State Survey Agency Directors

FROM: Director
Survey and Certification Group

SUBJECT: **Multiple Providers** - The National Provider Identifier (NPI)

Letter Summary

- The Centers for Medicare & Medicaid Services' (CMS) Administrator announced the May 23rd start of enumeration for the NPI in a letter to the health care community.

- The purpose of this letter is to 1) have providers apply for and receive an NPI beginning May 2005; 2) alert providers that use of the NPI in health care transactions is mandatory as of May 2007; and 3) alert providers that because some health plans may accept the NPI sooner, providers must pay close attention to plan/payer billing instructions.

- As State Survey Agency Directors, you are often a source for up-to-date compliance information. To assist you in announcing the NPI initiative to your respective constituents, we are providing you with outreach resources as listed below.

- Please make this information available to the providers you serve, who may directly or indirectly find this information useful.

1. CMS Administrative Announcement

The CMS Administrator announced a May 23, 2005 start of enumeration for the NPI. The NPI is the standard unique health identifier for health care providers that was adopted by the Secretary of Health and Human Services under the Health Insurance Portability and Accountability Act of 1996. The Administrator's announcement letter:

Informs health care providers about the NPI,
Describes three ways to obtain an NPI, and
Gives them guidance as to what they should do once they have obtained their NPI.

The letter, which also provides contacts and resources should health care providers have questions about the NPI, can be viewed at http://www.cms.hhs.gov/hipaa/hipaa2/npi_provider.asp on the CMS Web site. We have included the letter as an attachment to this memo.

Article for Medicare Providers about NPI Implementation

The Article for Medicare Providers about NPI Implementation can be found at http://www.cms.hhs.gov/medlearn/matters/mmarticles/2005/SE0528.pdf on the CMS Web site. We have included the article in this memo. This article is written for Fee-for-Service Medicare providers and contains language from the Administrator's letter to ALL providers plus qualifying information about the Medicare program's readiness for NPI implementation. If you are reaching out to non-Medicare constituents, (e.g., State

Medicaid agencies, private insurers), you may not want to use the article as written.

For questions concerning this memorandum, please contact Kim Roche at (410) 786-3524 or e-mail at kim.roche@cms.hhs.gov.

Effective date: Immediately. The State Survey Agency should disseminate this information over the next year, or make it available to providers using websites, newsletters, or other outreach forums already planned.

Training: This memorandum should be shared with State Survey Agency and Regional Office supervisory and training staff.

/s/
Thomas A. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachments

Medicare Learning Network
Medlearn Matters
Information for Medicare Providers
CMS
CENTERS for MEDICARE & MEDICAID SERVICES

Related Change Request (CR) #: N/A
Related CR Release Date: N/A

Medlearn Matters Number: SE0528

CMS Announces the National Provider Identifier (NPI) Enumerator Contractor and Information on Obtaining NPIs

Provider Types Affected

All health care providers - Medicare and non-Medicare

Provider Action Needed

Learn about the NPI and how and when to apply for one.

Background

The Centers for Medicare & Medicaid Services (CMS) is pleased to announce the availability of a new health care identifier for use in the HIPAA standard transactions.

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) mandated that the Secretary of Health and Human Services adopt a standard unique health identifier for health care providers. On January 23, 2004, the Secretary published a Final Rule that adopted the National Provider Identifier (NPI) as this identifier.

The NPI must be used by covered entities under HIPAA (generally, health plans, health care clearinghouses, and health care providers that conduct standard transactions). The NPI will identify health care providers in the electronic transactions for which the Secretary has adopted standards (the standard transactions) after the compliance dates. These transactions include claims, eligibility inquiries and responses, claim status inquiries and responses, referrals, and remittance advices.

The NPI will replace health care provider identifiers that are in use today in standard transactions. Implementation of the NPI will eliminate the need for health care providers to use different identification numbers to identify themselves when conducting HIPAA standard transactions with multiple health plans.

All health plans (including Medicare, Medicaid, and private health plans) and all health care clearinghouses must accept and use NPIs in standard transactions by May 23, 2007 (small health plans have until May 23, 2008). After those compliance dates, health care providers will use only their NPIs to identify themselves in standard transactions, where the NPI is required.

Important Note: While you are urged to apply for an NPI beginning May 23, 2005, the Medicare program is not accepting the NPI in standard transactions yet. Explicit instructions on time frames and implementation of the NPI for Medicare billing will be issued later in 2006.

Disclaimer
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NPI Enumerator Contract Awarded

Recently, the CMS announced the selection of Fox Systems, Inc. as the contractor, to be called the Enumerator, to perform the support operations for the NPI project.

Fox Systems, Inc. will process NPI applications from health care providers and operate a help desk to assist health care providers in obtaining their NPIs.

Who may apply for the NPI?

All health care providers including individuals, such as physicians, dentists, and pharmacists, and organizations, such as hospitals, nursing homes, pharmacies, and group practices are eligible to apply for and receive an NPI. **Note:** All health care providers who transmit health information electronically in connection with any of the HIPAA standard transactions are required by the NPI Final Rule to obtain NPIs. This is true even if they use business associates such as billing agencies to prepare the transactions.

The NPI Application Process

Health care providers may begin applying for an NPI on May 23, 2005. Once the process begins, **it will be important to apply for your NPI** before the compliance date of May 2007 because health plans could require you to use your NPI before that date.

You will be able to apply for your NPI in one of three ways:

1. You may apply through an easy-to-use Web-based application process, beginning May 23, 2005. The web address will be **https://nppes.cms.hhs.gov**, but **please note -- the web site is not available until May 23, 2005.**
2. Beginning July 1, 2005, you may complete a paper application and send it to the Enumerator. A copy of the application, including the Enumerator's mailing address (where you will send it) will be available on **https://nppes.cms.hhs.gov** or you can call the Enumerator to receive a copy. The phone number is 1-800-465-3203 or TTY 1-800-692-2326. **But remember, paper applications may not be submitted until July 1, 2005.**
3. With your permission, an organization may submit your application in an electronic file. This could mean that a professional association, or perhaps a health care provider who is your employer, could submit an electronic file containing your information and the information of other health care providers. **This process will be available in the fall of 2005.**

You may apply for an NPI using only one of these methods. When gathering information for your application, be sure that all of your information, such as your social security number and the Federal Employer Identification Number, are correct. Once you receive your NPI, safeguard its use.

If all information is complete and accurate, the Web-based process could result in you being issued a number within minutes. If there are problems with the information received, it could take longer . The paper application processing time is more difficult to estimate, depending on the information supplied in the application, the workload, and other factors.

The transition from existing health care provider identifiers to NPIs will occur over the next couple of years. Each health plan with which you conduct business, including Medicare, will notify you when it will be ready to accept NPIs in standard transactions like claims. You can expect to hear about the importance of

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applying for an NPI from a variety of sources. Be clear that you only have to apply for, and acquire, one NPI. Your unique NPI will be used for all standard transactions, Medicare and non-Medicare.

Please be particularly aware that applying for an NPI does not replace any enrollment or credentialing processes with any health plans, including Medicare.

Additional Information

For additional information on NPIs:

- Visit **http://www.cms.hhs.gov/hipaa/hipaa2** on the web.
- Beginning May 23, 2005, visit **https://nppes.cms.hhs.gov** or call the Enumerator at 1-800-465-3203 or TTY 1-800-692-2326.
- For HIPAA information, you may call the HIPAA Hotline: 1-866-282-0659, or write to **AskHIPAA@cms.hhs.gov** on the web.

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DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

CMS
CENTERS for MEDICARE & MEDICAID SERVICES

May 6, 2005

National Provider Identifier Activities Begin in 2005

Dear Health Care Provider:

The Centers for Medicare & Medicaid Services (CMS) is pleased to announce the availability of a new identifier for use in the standard electronic health care transactions. The National Provider Identifier (NPI) will be the single provider identifier, replacing the different provider identifiers you currently use for each health plan with which you do business. This identifier, which implements a requirement of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), must be used by most HIPAA covered entities, which are health plans, health care clearinghouses, and health care providers that conduct electronic transactions for which the Secretary has adopted a standard (i.e., standard transactions). This letter will help you to understand the background of this requirement and what steps you need to take to apply for and receive an NPI.

The NPI is one of the steps that CMS is taking to improve electronic transactions for health care. National standards for electronic health care transactions encourage electronic commerce in the health care industry and simplify the processes involved to reduce the administrative burdens on health care providers. With national standards and identifiers in place for electronic claims and other transactions, health care providers will be able to submit transactions to any health plan in the United States. Health plans will be able to send standard transactions such as remittance advices and referral authorizations to health care providers. These national standards will make electronic data interchange a viable and preferable alternative to paper processing for health care providers and health plans alike.

To date, we have adopted and implemented the following HIPAA standards: electronic health care transactions and code sets, privacy, security, and the national employer identifier.

We are now beginning to implement the NPI. On January 23, 2004, the Secretary published a Final Rule that adopted the NPI as this identifier. As of the compliance dates listed below, HIPAA covered entities must use NPIs to identify health care providers in standard transactions. These transactions include claims, eligibility inquiries and responses, claim status inquiries and responses, referrals, and remittance advices.

Health care providers include individuals, such as physicians, dentists, and pharmacists, and organizations, such as hospitals, nursing homes, pharmacies, and group practices. Health care providers who transmit health information electronically in connection with any of the standard transactions are required by the NPI Final Rule to obtain NPIs, even if they use business associates, such as billing agencies, to prepare the transactions.

The NPI will replace health care provider identifiers that are in use today in standard transactions. Implementation of the NPI will eliminate the need for health care providers to use different identification numbers to identify themselves when conducting standard transactions with multiple health plans. Many health plans, including Medicare, Medicaid, and private health insurance issuers, and all health care clearinghouses must accept and use NPIs in standard transactions by May 23, 2007. Small health plans have until May 23, 2008. After those compliance dates, health care providers may use only their NPIs to identify themselves in standard transactions, where the NPI is called for.

You will be able to apply for your NPI in one of three ways:

- You may apply through an easy web-based application process, beginning May 23, 2005. The web address is https://nppes.cms.hhs.gov.
- You may prepare a paper application and send it to the entity that will be assigning the NPI (the Enumerator) on behalf of the Secretary, beginning July 1, 2005. A copy of the application, including the Enumerator's mailing address, will be available on https://nppes.cms.hhs.gov. You may also call the Enumerator for a copy. The phone number is 1-800-465-3203 or TTY 1-800-692-2326.
- With your permission, an organization may submit your application in an electronic file. This could mean that a professional association or perhaps a health care provider who is your employer could submit an electronic file containing your information and the information of other health care providers. This process will be available in the fall 2005.

Remember, you may apply for an NPI using only one of the ways described above. When gathering information for your application, be sure that all of your information, such as your social security number and Federal employer identification number, are correct. Once you receive your NPI, safeguard its use. The application form contains a Privacy Act Statement, which explains how we may disseminate the information collected in the application.

You may receive notices about the NPI from many of the health plans with which you do business. Remember that you need apply only once for an NPI. The same NPI is used for every health plan.

The transition from existing health care provider identifiers to NPIs in standard transactions will occur over the next couple of years. We urge health care providers to apply for an NPI beginning on May 23, 2005. While the NPI must be used on standard transactions with health plans, other than small health plans, no later than May 23, 2007, health care providers should not begin using the NPI in standard transactions on or before the compliance dates until health plans have issued specific instructions on accepting the NPI. Health plans will notify you when you can begin using NPIs in standard transactions. You should be aware that health plans might request that you begin using your NPI prior to the compliance dates. Applying for an NPI does not replace any enrollment or credentialing processes with any health plan, including Medicare.

You may obtain information about the NPI at www.cms.hhs.gov/hipaa/hipaa2. This site contains Frequently Asked Questions and other information related to the NPI and other HIPAA standards.

Beginning May 23, 2005, we will also provide up-to-date information about the NPI, such as when and how to apply on the NPPES web site at https://nppes.cms.hhs.gov, or you may call the Enumerator at 1-800-465-3203 or TTY 1-800-692-2326.

Sincerely,

/s/

Mark B. McClellan, M.D., Ph.D.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard, Mail Stop S2-12-25
Baltimore, Maryland 21244-1850

Center for Medicaid and State Operations/Survey and Certification Group

Ref: S&C-05-33

DATE: June 9, 2005

TO: State Survey Agency Directors
State Fire Authorities

FROM: Director
Survey and Certification Group

SUBJECT: **Multiple Providers** - Hospitals, Ambulatory Surgical Centers, Nursing Homes, Religious Non-Medical Health Care Institutions, Programs of All-Inclusive Care for the Elderly (PACE) Facilities, Critical Access Hospitals, Intermediate Care Facilities for the Mentally Retarded – Adoption of a New Fire Safety Amendment for the Use of Alcohol Based Hand Rubs (ABHRs)

Letter Summary

- This letter highlights the publication of an amendment to the 2000 Life Safety Code for certain health care facilities.
- The amendment, and our implementing administrative rule, permit Alcohol Based Hand Rubs (ABHRs) to be used in exit access corridors provided they meet certain requirements.
- The use of ABHRs must conform to state and local laws.
- The dispensers must be installed in such to minimize leaks and/or spills.
- The dispenser(s) must be installed to adequately prevent access by vulnerable populations.

The purpose of this memorandum is notify states and regional offices of the publication on March 25, 2005 in the ***Federal Register*** (Vol. 70, No. 57, Page 15229) of an interim final rule with a comment period entitled: *"Medicare and Medicaid Programs: Fire Safety Requirements for certain Health Care Facilities; Amendment."* The 60-day comment period closed on May 24, 2005. We have attached a copy of the regulation to this memorandum.

Regulation Requirements:

The National Fire Protection Association (NFPA) recently amended the 2000 edition of the Life Safety Code (LSC), which is adopted by reference in the Medicare and Medicaid fire safety regulations, to permit the installation of ABHR dispensers in exit access corridors of health care facilities. Previously, ABHRs have been permitted in patient rooms, but not in egress corridors, since they contain flammable materials and could block egress in a fire.

ABHRs have become increasingly common as an infection control method. The Centers for Disease Control and Prevention reports there are more than 2 million health care acquired infections per year. Many of the infections are transmitted because health care workers do not wash their hands or do so improperly or inadequately.

An important aspect in getting health care workers to use ABHRs is their accessibility. The American Hospital Association commissioned a study to determine the safest method to place ABHRs in egress corridors. As a result of this study, the LSC was

amended to permit their use under certain conditions as outlined below.

Installation:

Where ABHR dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m).

The maximum individual dispenser fluid capacity shall be:

O 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.
0.5 gallons (2.0 liters) for dispensers in suites of rooms.

The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.

Not more than an aggregate 10 gallons (77.8 litters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.

Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquid Code*.

The dispensers shall not be installed over or directly adjacent to an ignition source.

In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

If you have any questions concerning this memorandum, please contact Mayer Zimmerman at 410-786-6839 or via E-mail at Mayer.Zimmerman@cms.hhs.gov.

Effective Date: This regulation was effective May 24, 2005. There is no phase-in period provided in the regulation. Please ensure that all staff are fully apprised of this information within 30 days.

Training: This information should be shared with all appropriate survey and certification staff, surveyors, their managers and state fire authorities and their staff.

/s/
Thomas E. Hamilton

cc: Survey and Certification Regional Office Management (G-5)

Attachment

Junction, Kentucky northward to its confluence with the Salt River. Otter Creek from Point D (latitude 37°51′31.77″ N; longitude 86°00′03.79″ W) located approximately 3.4 miles north of Vine Grove, Kentucky to Point E (latitude 37°55′21.95″ N; longitude 86°01′47.38″ W) located approximately 2.3 miles southwest of Muldraugh.

(b) *The regulation.* All persons, swimmers, vessels and other craft, except those vessels under the supervision or contract to local military or Army authority, vessels of the United States Coast Guard, and federal, local or state law enforcement vessels, are prohibited from entering the danger zones without permission from the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky or his/her authorized representative.

(c) *Enforcement.* The regulation in this section, promulgated by the United States Army Corps of Engineers, shall be enforced by the Commanding General, U.S. Army Garrison, Fort Knox Military Reservation, Fort Knox, Kentucky and/or other persons or agencies as he/she may designate.

Dated: March 16, 2005.

Michael B. White,

Chief, Operations, Directorate of Civil Works.

[FR Doc. 05–5904 Filed 3–24–05; 8:45 am]

BILLING CODE 3710–92–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

42 CFR Parts 403, 416, 418, 460, 482, 483, and 485

[CMS–3145–IFC]

RIN 0938–AN36

Medicare and Medicaid Programs; Fire Safety Requirements for Certain Health Care Facilities; Amendment

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Interim final rule with comment period.

SUMMARY: This interim final rule with comment period adopts the substance of the April 15, 2004 temporary interim amendment (TIA) 00–1 (101), *Alcohol Based Hand Rub Solutions*, an amendment to the 2000 edition of the Life Safety Code, published by the National Fire Protection Association (NFPA). This amendment will allow certain health care facilities to place alcohol-based hand rub dispensers in egress corridors under specified conditions. This interim final rule with comment period also requires that nursing facilities install smoke detectors in resident rooms and public areas if they do not have a sprinkler system installed throughout the facility or a hard-wired smoke detection system in those areas.

DATES: *Effective date:* These regulations are effective on May 24, 2005.

Comments date: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on May 24, 2005.

ADDRESSES: In commenting, please refer to file code CMS–3145–IFC. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of three ways (no duplicates, please):

1. *Electronically.* You may submit electronic comments on specific issues in this regulation to *http://www.cms.hhs.gov/regulations/ecomments.* (Attachments should be in Microsoft Word, WordPerfect, or Excel; however, we prefer Microsoft Word.)

2. *By mail.* You may mail written comments (one original and two copies) to the following address ONLY:

Centers for Medicare & Medicaid Services, Department of Health and Human Services, Attention: CMS–3145–IFC, P.O. Box 8018, Baltimore, MD 21244–8018.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. *By hand or courier.* If you prefer, you may deliver (by hand or courier) your written comments (one original and two copies) before the close of the comment period to one of the following addresses. If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786–9994 in advance to schedule your arrival with one of our staff members.

Room 445–G, Hubert H. Humphrey Building, 200 Independence Avenue, SW., Washington, DC 20201; or 7500 Security Boulevard, Baltimore, MD 21244–1850.

(Because access to the interior of the HHH Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by mailing your comments to the addresses provided at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the **SUPPLEMENTARY INFORMATION** section.

FOR FURTHER INFORMATION CONTACT: Danielle Shearer, (410) 786–6617; James Merrill, (410) 786–6998; or Mayer Zimmerman, (410) 786–6839.

SUPPLEMENTARY INFORMATION:

Submitting Comments: We welcome comments from the public on all issues set forth in this rule to assist us in fully considering issues and developing policies. You can assist us by referencing the file code CMS–3145–IFC and the specific "issue identifier" that precedes the section on which you choose to comment.

Inspection of Public Comments: Comments received timely will be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone (410) 786–9994.

I. Background

A. Alcohol-Based Hand Rubs (ABHR)

The Life Safety Code (LSC) is a compilation of fire safety requirements for new and existing buildings that is updated and generally published every 3 years by the National Fire Protection Association (NFPA), a private, nonprofit organization dedicated to reducing loss of life due to fire. The Medicare and Medicaid regulations have historically incorporated these requirements by reference, while providing the opportunity for a Secretarial waiver of a requirement under certain circumstances. The statutory basis for incorporating NFPA's LSC for our providers is under the Secretary's general rulemaking authority at sections 1102 and 1871 of the Social Security Act.

On January 10, 2003, we published a final rule in the **Federal Register**, entitled "Fire Safety Requirements for Certain Health Care Facilities" (68 FR

1374). In that final rule, we adopted the 2000 edition of the LSC provisions governing Medicare and Medicaid health care facilities. The Office of the Federal Register's rules regarding incorporation by reference state that the document so incorporated is the one referred to as it exists on the date of publication of the final rule. Among other things, the 2000 edition of the LSC prohibited the placement of accelerants, including alcohol-based hand rub (ABHR) dispensers, in egress corridors, but allowed their placement in patient rooms and other appropriate areas. We did not receive any public comments contesting this prohibition during the rulemaking process.

[If you choose to comment on issues in this section, please include the caption ''ABHR RESEARCH'' at the beginning of your comments.]

The ABHRs have become an increasingly common infection control method. The issue of infection control has been a concern identified in numerous research studies and reports. The Centers for Disease Control and Prevention (CDC) reports that there are more than 2 million health care acquired infections per year (*http://www.cdc.gov/handhygiene/firesafety/aha_meeting.htm*). Many of the microorganisms that cause these infections are transmitted to patients because health care workers do not wash their hands or do so improperly or inadequately. Improving hand hygiene is an important step towards reducing the number of health care acquired infections. In October 2002, the CDC posted hand hygiene guidelines for health care settings on its website (*http://www.cdc.gov/handhygiene/firesafety/default.htm*). The guidelines clearly recommended the use of ABHRs. The CDC stated that—

- Compared with soap and water hand washing, ABHRs are more effective in reducing bacteria on hands, cause less skin irritation/dermatitis, and save personnel time;
- Use of ABHRs has been associated with improved adherence to recommended hand hygiene practices;
- Adherence is directly tied to access. The highest possible adherence to hand hygiene practice is achieved when ABHR dispensers are in readily accessible locations such as the corridor near the patient room entrance and inside patient rooms; and
- Improved hand hygiene practices have been associated with reduced health care-associated infection rates.

Research from a variety of sources confirms the CDC's research and statements about the usefulness and effectiveness of ABHRs in health care facilities. For example, the study ''Improving adherence to hand hygiene practice: A multidisciplinary approach'' (Pittet D. Emerging Infectious Diseases. 2001 March–April; 7(2):243–40. Review) concludes that, ''[a]lcohol-based hand rub, compared with traditional handwashing with unmedicated soap and water or medicated hand antiseptic agents, may be better because it requires less time, acts faster, and irritates hands less often.''

The same study goes on to state that, ''[t]his method was used in the only program that reported a sustained improvement in hand hygiene compliance with decreased infection rates.'' The relationship between ABHRs and improved adherence to recommended hand hygiene practices is also found in other studies, including ''Availability of an alcohol solution can improve hand disinfection compliance in an intensive care unit'' (Maury E, *et al.* American Journal of Respiratory and Critical Care Medicine, 2000; 162:324–327). This study saw compliance with hand hygiene practice rates rise from 42.4 percent before the introduction of ABHRs to 60.9 percent after the introduction of ABHRs. Each category of health care provider, from nurses to physicians, and even patients increased compliance with hand hygiene practices.

Another study, ''Effectiveness of a hospital-wide programme to improve compliance with hand hygiene'' (Pittet D, Hugonnet S, Harbarth S, *et al.* Lancet 356. 2000; 1307–1312), also demonstrated an increase in compliance with hand hygiene practices that was directly related to the use of ABHRs. In this study, compliance rates rose from 47.6 percent to 66.2 percent over a 3-year period. Handwashing rates remained stable at 30 percent during this period while hand disinfection rates rose from 13.6 percent to 37.0 percent. During this time, the annual amount of ABHR use increased from 3.5L per 1,000 patients to 10.9L per 1,000 patients. The increase in hand disinfection through ABHRs and related increase in compliance with hand hygiene practices are directly tied to the increased availability and use of ABHRs.

An important aspect of getting health care workers and others to use ABHRs is their accessibility. In the study ''Handwashing compliance by health care workers: The impact of introducing an accessible, alcohol-based antiseptic'' (Bischoff WE, *et al.* Archives of Internal Medicine, 2000; 160: 1017–1021), researchers assessed how the accessibility of ABHRs impacted their use. The researchers found that when one ABHR dispenser was available for every four patient beds the adherence rate for hand hygiene was 19 percent before patient contact and 41 percent after patient contact. When one ABHR dispenser was available for each bed, the rates rise to 23 percent before patient contact and 48 percent after patient contact. Increased availability of ABHR dispensers resulted in increased hand hygiene rates.

The relationship between increased availability and increased use is likely the result of several factors. An increase in the number of ABHR dispensers acts as a continuous reminder to workers and others that they need to disinfect their hands. For example, each time an individual approaches a patient area, he or she may see, right next to the door, an ABHR dispenser. The dispenser reminds an individual to disinfect his or her hands. In addition to reminding an individual, the location of ABHR dispensers in obvious and highly visible locations serves as a convenient way to disinfect hands. Rather than repeatedly walking to a sink located in another area, a worker can use the ABHR as he or she enters a patient's room as well as while inside the room. Easy and immediate access to ABHR dispensers is a key element in improving adherence to hand hygiene practices.

Improving hand hygiene has a direct effect on the number of health care acquired infections. Following the introduction of ABHRs in one hospital, there was a reduction in the proportion of methicillin-resistant S. aureus infections for each of the quarters of 2000–2001, when ABHRs were utilized, compared with 1999–2000, when ABHRs were not utilized. There was also a 17.4 percent reduction in the incidence of Clostridium difficile-associated disease from 11.5 cases per 1,000 admissions before the introduction of ABHRs to 9.5 cases per 1000 admissions after the introduction of ABHRs (Gopal Rao G, Jeanes A, Cisnan M, *et al.* Marketing hand hygiene in hospitals: A case study. Journal of Hospital Infection 2002; 50:42–47).

[If you choose to comment on issues in this section, please include the caption ''ABHR SAFETY'' at the beginning of your comments.]

The benefits of using ABHRs have been well demonstrated. However, until a short time ago there were concerns about placing ABHR dispensers in egress corridors. The ABHRs are most commonly found in a gel form contained in a single use disposable bag that is inserted into a wall-mounted dispenser, similar in appearance to wall-mounted hand soap dispensers. The dispenser compresses the bag to

dispense the gel. During normal operation and replacement, the dispenser remains a closed system, meaning that vapors are not released into the atmosphere. In addition, refilling is done using single-use disposable bags rather than large bulk containers. The relatively small quantity of gel in each dispenser combined with the absence of vapor release means that these dispensers, when properly installed and used, pose little fire risk in health care facilities.

In July 2003, the American Hospital Association (AHA), in conjunction with the CDC, held a stakeholder meeting with representatives from more than 20 governmental and non-governmental agencies, including CMS, to discuss the issue of the placement and use of ABHRs. During the meeting, the AHA presented a fire modeling study that was conducted by Gage-Babcock & Associates, Inc. on behalf of the AHA's sister organization, the American Society for Healthcare Engineering (ASHE). This study demonstrated that placing ABHR dispensers in egress corridors is safe, provided that certain conditions are met *(http://www.hospitalconnect.com/ashe/currentevent/alcohol_based_hand_rub/Final_Report_rev1.2_Part_1_2.pdf).*

In February 2004, the ASHE submitted and received approval for temporary interim amendment (TIA) 00–1 (101), *Alcohol-Based Hand Rub Solutions,* to amend the 2003 edition of the LSC. This TIA permitted the placement of ABHR dispensers in egress corridors if certain criteria are met. During a meeting of the NFPA's Standards Council on April 15, 2004, TIA 00–1 (101) was approved for the 2003 edition of the LSC. The TIA was also approved for the 2000 edition of the LSC (the edition CMS adopted). The TIA altered chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC. The change became effective May 5, 2004.

Normally, when the NFPA amends the LSC, it amends the most recently published edition of the code. The most recently published edition is the 2003 edition. However, when the NFPA amended the LSC this time, it retroactively amended the 2000 edition of the LSC in addition to the 2003 edition of the LSC. This is the first time that the NFPA ever retroactively adopted an amendment for an earlier edition of the LSC.

We are adopting the amendment to chapters 18 and 19 of the 2000 edition of the LSC, specifically the changes to chapters 18.3.2.7 and 19.3.2.7. Adopting the amended chapters will allow health care facilities to place ABHR dispensers in egress corridors. We are not adopting the entire revised 2000 edition of the LSC. Anything in the non-amended version of the 2000 edition of the LSC that is contrary to the amended policy will not apply.

Chapters 18 and 19 will apply to hospitals, long-term care facilities, religious non-medical health care institutions, hospices, programs of all-inclusive care for the elderly, hospitals, intermediate care facilities for the mentally retarded, and critical access hospitals.

Ambulatory surgical centers (ASC) are not covered under chapters 18 or 19 of the LSC; but are rather covered under chapter 21 of the LSC. Many ASCs are interested in installing ABHR dispensers in corridors. However, chapter 21 of the LSC has not been amended thus far to permit the installation of ABHR dispensers in egress corridors in ASCs. We are allowing ASCs to install ABHR dispensers in egress corridors according to the same conditions identified for other health care facilities.

We consider a health care facility to be in compliance with our requirements if the placement of ABHR dispensers meets the specified conditions listed in section II.A of this interim final rule with comment period. The ABHR dispensers will also be required to meet the following criteria that are listed in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC:

* Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m).

* The maximum individual dispenser fluid capacity shall be:

—0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

—0.5 gallons (2.0 liters) for dispensers in suites of rooms.

* The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other.

* Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet.

* Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code.*

* The dispensers shall not be installed over or directly adjacent to an ignition source.

* In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

After careful and thorough consideration of the numerous studies and recommendations presented above, we believe that placing ABHR dispensers in all appropriate areas, including corridors, is safe and appropriate for patients and providers alike.

B. Smoke Detectors

A recent Government Accountability Office (GAO) report entitled ''Nursing Home Fire Safety: Recent Fires Highlight Weaknesses in Federal Standards and Oversight'' (GAO–04–660, July 16, 2004, *http://www.gao.gov/new.items/d04660.pdf)* examined two long-term care facility fires in 2003 that resulted in 31 resident deaths. The report examined Federal fire safety standards and enforcement procedures, as well as results from fire investigations of these two incidents. The report recommended that fire safety standards for unsprinklered facilities be strengthened. It specifically cited requiring smoke detectors in these facilities as one way to strengthen the requirements.

The fires, in Hartford, Connecticut and Nashville, Tennessee, had several things in common. Each fire began in a resident sleeping room at night, neither of these rooms had a smoke detector, and the majority of victims died from smoke inhalation. The lack of smoke detectors in resident rooms, the report concludes, ''* * * may have delayed staff response and activation of the buildings' fire alarms.''

Relying on an effective and timely staff response is a crucial aspect of the current facility fire safety requirements. Long-term care facilities are required by the LSC (chapters 18.7.1.1 and 19.7.1.1) to have an emergency plan that will be implemented in the event of a fire at the facility. As part of this plan, staff members at Medicare-approved facilities are typically expected to do things such as close resident room doors, turn off fans and other air circulation devices, and evacuate residents.

However, battery-operated smoke detectors, a basic fire safety device, are only required by the 2000 edition of the Life Safety Code to be installed in existing non-sprinklered resident rooms when those rooms contain furniture that the resident has brought from his or her home. This was not the case in either fire; therefore, smoke detectors were not in the resident sleeping rooms where the fires started and staff members were not aware of the fires until smoke reached the smoke detectors in the

corridors. This delay inhibited timely staff response and may have contributed to resident deaths.

While resident rooms are the leading area of fire origin, fires can and do originate in other areas. For example, a fire could originate in an unoccupied resident activity room. As with resident sleeping rooms, there is a possibility that no one will be aware of this fire until its smoke spread to a corridor where there are smoke detectors. By this time, smoke may have also begun filtering into other areas of the facility such as resident sleeping rooms and public areas that are occupied, thus harming those residents. In order to alert staff and residents in the earliest stages of a fire, we believe that it is necessary to install smoke detectors in resident sleeping rooms and public areas. For these reasons, we are requiring that long-term care facilities that do not have sprinklers must at least install battery-operated smoke detectors in patient rooms and public areas. We have discussed this issue in detail in section II.B of this interim final rule with comment period.

We are specifically soliciting public comment on the placement of smoke detectors in long-term care facilities. Should detectors also be placed in non-public areas such as storage rooms, closets, and offices?

Facilities that choose to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code,* in patient rooms and public areas within the 1 year phase-in period discussed in section II.B of this interim final rule with comment period will be exempt from this requirement. A hard-wired smoke detector system is a system that is wired to both a facility's electrical and fire alarm systems. The detectors draw their energy from a facility's electrical system and use batteries as back-ups in case of power failure. In addition, the detectors communicate with one another so that an alarm in one room would trigger an alarm in every room. The detectors also communicate with the facility's fire alarm system, thus notifying the fire department of the situation. If a facility chose to install a hard-wired system in resident rooms and public areas, then it will not have to install battery-operated smoke detectors because such a system will exceed the requirements of this interim final rule with comment period. Facilities that have installed sprinkler systems throughout in accordance with NFPA 13, *Automatic Sprinklers,* will also be exempt from the proposed requirement to install smoke detectors, because such a system will exceed this requirement.

C. Requirements for Issuance of Regulations

Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amended section 1871(a) of the Act and requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish timelines for the publication of Medicare final regulations based on the previous publication of a Medicare proposed or interim final regulation. Section 902 of the MMA also states that the timelines for these regulations may vary but shall not exceed 3 years after publication of the preceding proposed or interim final regulation except under exceptional circumstances. We intend to publish the final rule within the 3-year timeframe established under section 902 of the MMA.

II. Provisions of the Interim Final Rule

A. Alcohol-Based Hand Rubs

[If you choose to comment on issues in this section, please include the caption ''PLACEMENT REQUIREMENTS'' at the beginning of your comments.]

For the reasons specified in the preamble, in sections I.A. and I.B. above, we are modifying the conditions of participation for the following facilities:

—Religious non-medical health care institutions (RNHCI) (new § 403.744(a)(4)).
—Ambulatory Surgical Services (ASC) (new § 416.44(b)(5)).
—Hospices (new § 418.100(d)(6)).
—Programs of all-inclusive care for the elderly (PACE) (new § 460.72(b)(6)).
—Hospitals (new § 482.41(b)(9)).
—Long-term care (LTC) facilities (new § 483.70(a)(6)).
—Intermediate care facilities for the mentally retarded (ICFs/MR) (revised § 483.470(j)(7)).
—Critical access hospitals (CAHs) (new § 485.623(d)(7)).

The numbering that appears above corresponds to the most recent changes to the Life Safety Code regulations, published in the **Federal Register** as a final rule on August 11, 2004.

Specifically, we are adding a new provision that will allow these facilities to place ABHR dispensers in various locations, including egress corridors, if the facilities met the following conditions:

• The use of ABHR dispensers could not conflict with any State or local codes that prohibit or otherwise restrict the placement of ABHR dispensers in health care facilities. Allowing ABHR dispensers to be installed in egress corridors will be a significant lessening of restrictions. States and/or local jurisdictions may choose to retain stricter codes that prohibit or otherwise restrict the installation of ABHR dispensers in health care facilities. Facilities will still be required to comply with those stricter State and local codes. Therefore, facilities could only install ABHR dispensers if the dispensers were also permitted by State and local codes.

• The dispensers were installed in a manner that minimized leaks and spills that could lead to falls. Like soap, ABHRs are very slick. As such, it is more likely for someone to slip and fall on a surface that is covered by an ABHR solution than on a surface that is clean.

The increased risk of falls posed by the presence of leaky or spilled ABHR dispensers might be compounded by the medical conditions of patients or residents. While a healthy individual may fall and only suffer a bruise, a frail individual may suffer a broken hip. It is the specific safety needs of the patient populations found in hospitals and other health care facilities that necessitates the requirement that facilities take extra steps to ensure that ABHR dispensers do not leak or spill.

In addition to any extra steps such as additional hardware installation, facilities should follow all manufacturer maintenance recommendations for ABHR dispensers. Regular maintenance of dispensers in accordance with the directions of the manufacturer is a crucial step towards ensuring that the dispensers do not leak or spill.

• The dispensers were installed in a manner that adequately protected against access by vulnerable populations, such as residents in psychiatric units. There are certain patient or resident populations, such as residents of dementia wards, who may misuse ABHR solutions, which are both toxic and flammable. As a toxic substance, ABHR solutions are very dangerous if they are ingested, placed in the eyes, or otherwise misused. As a flammable substance, ABHR solutions could be used to start fires that endanger the lives of patients and destroy property.

Due to disability or disease, some patients are more likely to harm themselves or others by misusing ABHR solutions. In order to avoid any and all dangerous situations, a facility will have to take all appropriate precautions to secure the ABHR dispensers from misuse by these vulnerable populations.

• The dispensers were installed in accordance with chapters 18.3.2.7 and

19.3.2.7 of the 2000 edition of the LSC. The revisions to the chapters were thoroughly examined by the NFPA's fire safety experts and are based on the fire modeling study conducted by Gage-Babcock for the ASHE. As noted above, the study demonstrated that ABHR dispensers installed in egress corridors do not increase the risk of fire if certain conditions, as outlined in chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC, are met. The study also showed that if those conditions are not met, there will be an increase in the risk of fire.

B. Smoke Detectors

[If you choose to comment on issues in this section, please include the caption ''LOCATION'' at the beginning of your comments.]

We are requiring in § 483.70(a)(7) that long-term care facilities will, at minimum, be required to install battery-operated smoke detectors in resident sleeping rooms and public areas, unless they have a hard-wired smoke detector system in resident rooms and public areas or a sprinkler system throughout the facility. We are also requiring that facilities that install battery-operated smoke detectors have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Smoke detectors, when properly installed and maintained in resident sleeping rooms and public areas, are a basic, useful and effective fire safety tool.

We believe that at least installing battery-operated smoke detectors will provide earlier warning for facility residents and staff. Fires that originate in these areas will be detected earlier because the detector will be located closer to the fire's origin than if it were only placed in the corridor. Earlier detection, and thus earlier alarm, will allow residents and staff more time to react to the situation and implement the facility's emergency plan. Implementing the emergency plan typically includes notifying the fire department, and this earlier notification will speed the arrival of help. These factors could help to reduce the loss of life in a nursing facility fire.

[If you choose to comment on issues in this section, please include the caption ''MAINTENANCE'' at the beginning of your comments.]

As discussed earlier, a facility will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. Detectors require maintenance every 6 months to 1 year in order to ensure that the batteries are operating at optimum power. A detector with a depleted battery provides no protection. Thus, a regular maintenance program for the detectors is crucial to ensuring that residents and staff are indeed protected. Facilities will be expected to add maintenance of smoke detectors to their existing maintenance schedule.

[If you choose to comment on issues in this section, please include the caption ''1 YEAR PHASE-IN'' at the beginning of your comments.]

We are allowing facilities 1 year to comply with this regulation for two reasons. First, allowing facilities an extra year to comply with this regulation will also give interested facilities additional time to purchase and install a hard-wired smoke detector system or a sprinkler system. Purchasing and installing these systems is more complicated than purchasing and installing battery-operated detectors. Therefore, facilities that wanted to exercise this option would be prohibited from doing so if they were required to comply immediately. The 1-year phase-in will give facilities a chance to purchase and install a more advanced fire and smoke protection system than this regulation requires. We are strongly in favor of facilities taking advantage of this extended compliance period to install more advanced fire protection systems than the battery-operated smoke detectors that are required by this regulation.

Second, some facilities might have difficulty obtaining and installing battery-operated smoke detectors within the typical 60-day period from the date of publication of a final rule to the rule's effective date. Therefore, we are allowing facilities to phase-in smoke detectors over a 1-year period from the effective date of a final regulation. Facilities could use this year to purchase and install battery-operated detectors, or they could do so on an abbreviated schedule. We encourage facilities that choose to install battery-operated smoke detectors to do so as quickly as possible in order to increase fire safety. We believe that this phase-in period will give facilities more flexibility in meeting this requirement.

[If you choose to comment on issues in this section, please include the caption ''EXCEPTIONS'' at the beginning of your comments.]

The regulation will have two exceptions, one for facilities that have hard-wired smoke detection systems and one for facilities that have sprinkler systems. Hard-wired smoke detector systems installed in resident rooms and public areas will protect the same areas as the battery-operated detectors. Therefore, having both hard-wired and battery-operated detectors in these areas will be redundant, unnecessary, and overly burdensome. Facilities may still choose to use battery-operated detectors along with hard-wired detectors as an additional layer of fire protection, but we will not require the facilities to do so in this interim final rule with comment period.

Likewise, having both a sprinkler system throughout and battery-operated smoke detectors in resident rooms and public areas will duplicate fire safety efforts.

Sprinklers are considered to be the best way to protect building occupants in fires. Their response time and their ability to extinguish fires before they become a significant hazard will make battery-operated smoke detectors an unnecessary requirement. Facilities may still choose to use detectors as an additional layer of fire protection beyond sprinklers, but they will not be required to do so in this interim final rule with comment period.

III. Response to Comments

Because of the large number of public comments we normally receive on **Federal Register** documents, we are not able to acknowledge or respond to them individually. We will consider all comments we receive by the date and time specified in the **DATES** section of this preamble, and, when we proceed with a subsequent document, we will respond to the comments in the preamble to that document.

IV. Waiver of Proposed Rulemaking

We ordinarily publish a notice of proposed rulemaking in the **Federal Register** and invite public comment on the proposed rule. The notice of proposed rulemaking includes a reference to the legal authority under which the rule is proposed, and the terms and substances of the proposed rule or a description of the subjects and issues involved. This procedure can be waived, however, if an agency finds good cause that a notice-and-comment procedure is impracticable, unnecessary, or contrary to the public interest and incorporates a statement of the finding and its reasons in the rule issued.

We believe that continuing to prohibit the placement of ABHR dispensers in all appropriate areas, including egress corridors, is contrary to the public interest because ABHRs are a safe and effective method for increasing hand hygiene compliance rates, and their use has been shown to help decrease health care-acquired infections. As the studies and recommendations described in section I.A of this document

demonstrate, ABHRs are a safe and effective method for cleansing hands.

Although ABHR dispensers were once considered to be a fire safety risk when placed in egress corridors, they are no longer considered by fire safety experts to pose a significant risk to patient safety. According to the Gage-Babcock study, ABHR dispensers can be safely installed in egress corridors if they meet certain specifications, such as being placed at least 4 feet apart and not being placed over carpet in an unsprinklered smoke compartment. Fire safety experts believe that dispensers of ABHRs, when installed properly in egress corridors, do not decrease fire safety. We agree with this position.

Any fire safety concerns are, we believe, more than offset by the potential for health care facilities to improve their infection control practices. As the availability of ABHRs increases in a facility, so does the rate of hand hygiene compliance. An increase in hand hygiene compliance rates results in a decrease in health care acquired infections. We believe that the public will benefit from more ABHR dispensers being available in more places because the increased availability of ABHR dispensers will likely decrease the number of health care acquired infections, thus improving public health and safety in health care facilities.

We believe that allowing long-term care facilities to continue to care for residents in buildings that have neither sprinklers nor smoke detectors is contrary to the public interest because buildings that do not at least have smoke detectors present a greater risk of death or injury due to fire. In 2003, 31 long-term care facility residents died in two separate fires in buildings that did not have smoke detectors in patient rooms, where both fires started, or in public areas. Smoke detectors are basic and relatively inexpensive fire safety tools that have been proven to be effective at alerting residents and staff to fire, and that have been in use in homes and other buildings across the country for several decades. They provide early warning to occupants and have saved countless lives. Continuing to allow long-term care facilities that care for residents in buildings lacking smoke detectors risks the safety of all residents and staff in these buildings.

Therefore, we find good cause to waive the notice of proposed rulemaking and to issue this final rule on an interim basis. We are providing a 60-day public comment period.

V. Collection of Information Requirements

This document does not impose information collection and recordkeeping requirements. Consequently, it need not be reviewed by the Office of Management and Budget under the authority of the Paperwork Reduction Act of 1995.

VI. Regulatory Impact Statement

A. Overall Impact

We have examined the impact of this rule as required by Executive Order 12866 (September 1993, Regulatory Planning and Review), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and Executive Order 13132.

Executive Order 12866 (as amended by Executive Order 13258, which merely reassigns responsibility of duties) directs agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year). We have examined the impact of this interim final rule with comment period, and we have determined that this rule is neither expected to meet the criteria to be considered economically significant, nor do we believe it will meet the criteria for a major rule.

The RFA requires agencies to analyze options for regulatory relief of small businesses. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and small government jurisdictions. Most hospitals and most other providers and suppliers are small entities, either by nonprofit status or by having revenues of $6 million to $29 million in any 1 year. For purposes of the RFA, most entities affected by this interim final rule with comment period are considered small businesses according to the Small Business Administration's size standards, with total revenues of $29 million or less in any 1 year (for details, see 65 FR 69432). Individuals and States are not included in the definition of a small entity. According to CMS statistics, nursing facilities, which we require to install smoke detectors in resident rooms and public areas, earned a total of $89.6 billion in 1999 (*http://www.cms.hhs.gov/statistics/nhe/historical/t7.asp*). According to the National Nursing Home Survey: 1999 Summary (*http://www.cdc.gov/nchs/data/series/sr_13/sr13_152.pdf*), there were 18,000 nursing facilities in operation at that time. An average facility at this time thus had revenue of approximately $4,977,778. A facility with revenue 50 percent below this average still earned $2,488,889. In the first year, this interim final rule with comment period will cost, on average, approximately $9,800 per facility. In the following years, this interim final rule with comment period will cost $2,800 annually for maintenance. This amount will be less than one half of one percent of the total revenue for an average- or below-average-revenue facility. Therefore, we certify that this interim final rule with comment period will not have a significant impact on a substantial number of small entities. We are not considering hospitals or other facilities affected by the alcohol-based hand rub regulation in this regulatory flexibility analysis because we do not require those facilities to take any action. We are requiring that, if those facilities choose to install ABHR dispensers in egress corridors, then they will have to do so in accordance with the regulation.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds. This interim final rule with comment period will not have a significant impact on small rural hospitals because the interim final rule with comment period will not impose requirements on small rural hospitals.

Section 202 of the Unfunded Mandates Reform Act of 1995 also requires that agencies assess anticipated costs and benefits before issuing any rule that may result in expenditure in any 1 year by State, local, or tribal governments, in the aggregate, or by the private sector, of $110 million. This interim final rule with comment period will not have an effect on State, local, or tribal governments, and the private sector costs will not be greater than the $110 million threshold.

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates an interim final rule with comment period (and subsequent final rule) that imposes substantial direct requirement costs on

State and local governments, preempts State law, or otherwise has Federalism implications. This regulation does not have any Federalism implications.

B. Anticipated Effects

1. Alcohol-Based Hand Rubs

This interim final rule with comment period does not require an affected facility to install ABHR dispensers; thus, the facility will not be mandated with a burden associated with this provision of the regulation.

We, however, will require facilities that choose to install ABHR dispensers to do so in accordance with chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA. Facilities will have to install them in accordance with the LSC, and in a way that minimized leaks and spills, and access to the dispensers by vulnerable populations. Installing dispensers according to the specifications of the LSC and this regulation may increase installation costs. Facilities that choose to install dispensers are required by this regulation to take additional steps to minimize dispenser leaks and spills. While this regulation does not require a specific method for minimizing leaks and spills, facilities may decide to install additional hardware to ensure compliance with this regulation. Additional hardware, such as a device below the dispenser to catch drips, could increase purchasing and installation costs. The leak and spill minimization requirement is new, therefore we have no data to estimate the cost of the provision. We believe that any additional costs are small when compared to the costs of caring for a frail patient who fell on a slippery, ABHR covered floor.

In addition, the installation of these dispensers in egress corridors was previously prohibited. The requirements for locating dispensers in other areas will not change. Therefore, a facility will not have to relocate or modify existing dispensers to conform to the specifications.

Facilities that choose to install ABHR dispensers in any area, including corridors and patient rooms, are required by the LSC to store large quantities of ABHR solution in a flammable liquids cabinet. Facilities are required to use these cabinets if they choose to store 5 gallons or more of ABHR solution in a single smoke compartment. This LSC requirement helps ensure that large amounts of ABHR solution do not accelerate health care facility fires.

Most hospitals already have these cabinets to store other alcohol products or flammables, and would therefore not need to purchase a special storage container for ABHR solutions. Other facilities that may choose to install ABHR dispensers are typically smaller than hospitals and would not need to store more than five gallons of ABHR solution in a single smoke compartment. A facility with 20 rooms per smoke compartment will likely install 10 ABHR dispensers, for a total of three gallons of ABHR solution per smoke compartment. That same facility would be permitted to keep an additional two gallons of ABHR solution for refilling in that same compartment without using a flammable liquids cabinet. Therefore, we do not believe that this LSC provision will pose a significant burden to facilities that choose to install ABHR dispensers.

Facilities that choose to install ABHR dispensers may expect to see a decrease in health care acquired infections due to an increase in hand hygiene practices by clinicians and non-clinicians. While we cannot quantify the potential benefit of this decrease in infections, we do know that decreasing infection rates lead to better patient care outcomes and decrease patient care costs.

2. Smoke Detectors

The July 2004 GAO report estimated that 20 to 30 percent of long-term care facilities do not have sprinklers throughout the facility and will therefore be subject to the provisions of this regulation. We do not have information on the number of facilities that have a hard-wired smoke detector system in resident rooms and public areas. For the purposes of our analysis, we estimated that 25 percent of long-term care facilities, or 4,200, will be subject to the provisions of this regulation. We estimate that an average long-term care facility in a building that does not have sprinklers has 100 residents in 50 two-person resident sleeping rooms, and that each room will require one battery-operated smoke detector. We estimated that each average facility will require 20 additional detectors for public areas, for a total of 70 detectors per facility. We estimated that the cost of each smoke detector and its installation will be approximately $100. Therefore, an average facility will expect to pay $7,000 to purchase and install battery-operated smoke detectors in resident sleeping rooms and public areas. The total industry cost for purchasing and installing battery-operated smoke detectors in the specified areas will be $29,400,000.

Following installation of battery-operated smoke detectors in the specified areas, a long-term care facility will be required to have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors. We estimate that a facility will conduct monthly tests of each detector by activating the test button. This will take approximately 5 minutes per smoke detector per test, or 1 hour per smoke detector per year.

In addition, we estimate that a facility will clean each detector and change its batteries two times per year. This will take 15 minutes per smoke detector per cleaning and replacement, or 30 minutes per smoke detector per year. We estimate that the total annual maintenance time per detector will be one 1.5 hours, for total of 105 hours per average facility.

We estimate that the cost for this provision for an average long-term care facility with 70 smoke detectors, based on a maintenance person earning $20 per hour and $5 for batteries per change, is $2,800. The annual industry total for this maintenance provision will thus be $11,760,000.

The total cost for the first year of this regulation, including purchase, installation and maintenance costs, will be $9,800 per average facility, for a total of $41,160,000 industry wide. The cost for the following years of maintenance will be $2,800 per average facility annually, or $11,760,000 industry wide annually.

C. Alternatives Considered

1. Alcohol-Based Hand Rubs

We considered not adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC as amended by the TIA, thereby continuing to prohibit the placement of ABHR dispensers in egress corridors. However, continuing this prohibition was not acceptable for two reasons. First, we want to improve hand hygiene practices in order to reduce health-care-acquired infections. Hand hygiene levels increase when the availability of hygiene stations, such as ABHR dispensers, increase. It is helpful to have these stations in areas that are highly visible and easily accessed, as they are in corridors. Therefore, the potential to increase hand hygiene and thus decrease health care acquired infections by placing ABHR dispensers in all appropriate locations warranted this regulation.

Second, continuing to prohibit ABHR dispensers in egress corridors is contrary to our goal of increasing provider flexibility. We believe that, wherever possible, providers should be allowed the flexibility to meet the needs of their patients/residents in the manner they see fit. Providers are aware of the

hazards posed by infections and have developed many methods for addressing those hazards. The ABHR dispensers are one method, and we believe that providers should be allowed to utilize the ABHR dispensers to the fullest extent within the context of patient safety.

We also considered adopting chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC without the additional requirements. However, the chapters do not address several important areas of patient safety, and we believe that not addressing these areas may put patient safety at risk. The NFPA is dedicated to reducing loss of life due to fires. As such, it concerned itself solely with the fire safety implications of installing ABHR dispensers in egress corridors. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address leaks and spills that will result in people slipping and falling, nor did they address the potential for inappropriate use of ABHRs by vulnerable populations such as patients in ICFs/MR or dementia units. Due to disability or illness, these populations require additional protection from substances that are toxic and/or flammable. The ABHRs are both toxic and flammable. Chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC did not address these non-fire safety issues. Therefore, we believe that it is necessary to add other installation requirements in addition to chapters 18.3.2.7 and 19.3.2.7 of the 2000 edition of the LSC.

2. Smoke Detectors

We considered not requiring long-term care facilities to install smoke detectors; however, we believe that installation of the smoke detectors will help save lives. The July 2004 GAO report clearly outlined the role that smoke detectors, one of the most basic and effective fire safety devices available, played in the Nashville and Hartford fires. The report also outlined the wider role that detectors can and should play in long-term care facility fire safety. The positive impact of smoke detectors on resident safety, we believe, warrants their installation.

We also considered requiring long-term care facilities to immediately install battery-operated smoke detectors, rather than allowing facilities to phase them in over a 1-year period. We strongly support a facility's choice to install a fire safety system that exceeds the requirements of this regulation. It would have been extremely difficult for facilities that wanted to install hard-wired smoke detector systems or sprinkler systems to complete their tasks in 60 days. The 1-year phase-in period will allow those facilities more time to complete these systems, which would go beyond what we are requiring in this rule.

In addition, requiring facilities to, at a minimum, install battery-operated smoke detectors in 60 days would have posed a significant time and financial burden to facilities. Had we chosen this option, we would have required facilities to purchase and install a fairly large volume of detectors in a fairly short period of time, 60 days. This may have been very difficult for some facilities due to the initial cost of purchasing and installing the detectors. We estimate that it will cost facilities $7,000 to purchase and install battery-operated smoke detectors. There may be facilities that do not have the full amount of funds immediately available, and therefore would not be able to comply with this regulation within the standard 60-day time period. The 1-year phase-in period allows these facilities to distribute the cost over 12 months, for an average monthly cost of $584. Distributing the cost of smoke detectors over a 1-year period ensures that all facilities are able to afford the cost of complying with this rule.

Furthermore, we considered requiring long-term care facilities to install a hard-wired smoke detector system in accordance with NFPA 72, *National Fire Alarm Code*, for hard-wired alternating current smoke detector systems. This option would have posed a significant burden to some long-term care facilities because of the cost and time associated with purchasing and installing these devices. Hard-wired detectors must be wired directly into the facility's electrical and fire alarm system. We believe that the costs associated with purchasing this system and the time required to install it would have placed this option out of reach for some nursing facilities.

Therefore, we are requiring only the less expensive and less time consuming battery-operated detector. Facilities may still choose to install a hard-wired smoke detector system, and we encourage them to do so. Installation of such a system in patient rooms and public areas will exempt a facility from installing battery-operated detectors in those areas.

Finally, we considered requiring long-term care facilities that do not have sprinklers to install them. We are aware that the NFPA and long-term care industry are carefully examining this issue in light of the recent fires. We are also aware that installing sprinklers in existing facilities is an expensive proposition. We believe that this issue warrants further examination, and are committed to working with NFPA, the long-term care facility industry, and advocates to develop a consensus position. Any new sprinkler requirements would be discussed in a separate regulatory document and would be published in the **Federal Register**. Facilities may still choose to install a sprinkler system throughout the facility in accordance with NFPA 13. Installation of such a system will exempt a facility from installing battery-operated detectors in patient rooms and public areas. We encourage all facilities to fully explore this option, as it provides the highest level of fire protection currently available.

D. Conclusion

For these reasons, we are not preparing analyses for either the RFA or section 1102(b) of the Act because we have determined that this rule will not have a significant economic impact on a substantial number of small entities or a significant impact on the operations of a substantial number of small rural hospitals.

In accordance with the provisions of Executive Order 12866, this regulation was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 403

Grant programs—health, Health insurance, Hospitals, Intergovernmental relations, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 416

Health facilities, Incorporation by reference, Kidney diseases, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 460

Aged, Health care, Health records, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 482

Grant programs—health, Hospitals, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 483

Grant programs—health, Health facilities, Health professions, Health records, Medicaid, Medicare, Nursing homes, Nutrition, Reporting and recordkeeping requirements, Safety.

42 CFR Part 485

Grant programs—health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements

■ For the reasons set forth in the preamble, the Centers for Medicare and Medicaid Services amends 42 CFR chapter IV as set forth below:

PART 403—SPECIAL PROGRAMS AND PROJECTS

■ 1. The authority citation for part 403 is amended to read as follows:

Authority: 42 U.S.C. 1395b–3 and Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart G—Religious Nonmedical Health Care Institutions—Benefits, Conditions of Participation, and Payment

■ 2. Add new paragraphs (a)(3) and (a)(4) to § 403.744 to read as follows:

§ 403.744 Condition of participation: Life safety from fire.

(a) * * *

(3) [Reserved]

(4) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, the RNHCI may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 416—AMBULATORY SURGICAL SERVICES

■ 3. The authority citation for part 416 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Specific Conditions for Coverage

■ 4. Add new paragraph (b)(5) to § 416.44 to read as follows:

§ 416.44 Conditions for coverage-Environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, an ASC may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with the following provisions:

(A) Where dispensers are installed in a corridor, the corridor shall have a minimum width of 6 ft (1.8m);

(B) The maximum individual dispenser fluid capacity shall be:

(1) 0.3 gallons (1.2 liters) for dispensers in rooms, corridors, and areas open to corridors.

(2) 0.5 gallons (2.0 liters) for dispensers in suites of rooms;

(C) The dispensers shall have a minimum horizontal spacing of 4 ft (1.2m) from each other;

(D) Not more than an aggregate 10 gallons (37.8 liters) of ABHR solution shall be in use in a single smoke compartment outside of a storage cabinet;

(E) Storage of quantities greater than 5 gallons (18.9 liters) in a single smoke compartment shall meet the requirements of NFPA 30, *Flammable and Combustible Liquids Code;*

(F) The dispensers shall not be installed over or directly adjacent to an ignition source; and

(G) In locations with carpeted floor coverings, dispensers installed directly over carpeted surfaces shall be permitted only in sprinklered smoke compartments.

* * * * *

PART 418—HOSPICE CARE

■ 5. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart E—Conditions of Participation: Other Services

■ 6. Add a new paragraph (d)(6) to § 418.100 to read as follows:

§ 418.100 Condition of participation: Hospices that provide inpatient care directly.

* * * * *

(d) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospice may place alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this

amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 460—PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)

■ 7. The authority citation for part 460 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395).

Subpart E—PACE Administrative Requirements

■ 8. Add a new paragraph (b)(5) to § 460.72 to read as follows:

§ 460.72 Physical environment.

* * * * *

(b) * * *

(5) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a PACE center may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 482—CONDITIONS OF PARTICIPATION FOR HOSPITALS

■ 9. The authority citation for part 482 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart C—Basic Hospital Functions

■ 10. Add a new paragraph (b)(9) to § 482.41 to read as follows:

§ 482.41 Condition of participation: Physical environment.

* * * * *

(b) * * *

(9) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

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PART 483—REQUIREMENTS FOR STATES AND LONG TERM CARE FACILITIES

■ 11. The authority citation for part 483 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

Subpart B—Requirements for Long Term Care Facilities

■ 12. In § 483.70, add new paragraphs (a)(6) and (a)(7) to read as follows:

§ 483.70 Physical environment.

(a) * * *

(6) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a long-term care facility may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

(7) A long-term care facility must:

(i) Install battery-operated smoke detectors in resident sleeping rooms and public areas by May 24, 2006.

(ii) Have a program for testing, maintenance, and battery replacement to ensure the reliability of the smoke detectors.

(iii) Exception:

(A) The facility has a hard-wired AC smoke detection system in patient rooms and public areas that is installed, tested, and maintained in accordance

with NFPA 72, *National Fire Alarm Code,* for hard-wired AC systems; or

(B) The facility has a sprinkler system throughout that is installed, tested, and maintained in accordance with NFPA 13, *Automatic Sprinklers.*

* * * * *

Subpart I—Conditions of Participation for Intermediate Care Facilities for the Mentally Retarded

■ 13. Revise paragraph (j)(7) to § 483.470 to read as follows:

§ 483.470 Condition of participation: Physical environment.

* * * * *

(j) * * *

(7) *Facilities that meet the LSC definition of a health care occupancy.*

(i) After consideration of State survey agency recommendations, CMS may waive, for appropriate periods, specific provisions of the Life Safety Code if the following requirements are met:

(A) The waiver would not adversely affect the health and safety of the clients.

(B) Rigid application of specific provisions would result in an unreasonable hardship for the facility.

(ii) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a facility may install alcohol-based hand rub dispensers if—

(A) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(B) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(C) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(D) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the changes.

* * * * *

PART 485—CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

■ 14. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

Subpart F—Conditions of Participation: Critical Access Hospitals (CAHs)

■ 15. Add a new paragraph (d)(7) to § 485.623 to read as follows:

§ 485.623 Condition of participation: Physical plant and environment.

* * * * *

(d) * * *

(7) Notwithstanding any provisions of the 2000 edition of the Life Safety Code to the contrary, a critical access hospital may install alcohol-based hand rub dispensers in its facility if—

(i) Use of alcohol-based hand rub dispensers does not conflict with any State or local codes that prohibit or otherwise restrict the placement of alcohol-based hand rub dispensers in health care facilities;

(ii) The dispensers are installed in a manner that minimizes leaks and spills that could lead to falls;

(iii) The dispensers are installed in a manner that adequately protects against access by vulnerable populations; and

(iv) The dispensers are installed in accordance with chapter 18.3.2.7 or chapter 19.3.2.7 of the 2000 edition of the Life Safety Code, as amended by NFPA Temporary Interim Amendment 00–1(101), issued by the Standards Council of the National Fire Protection Association on April 15, 2004. The Director of the Office of the Federal Register has approved NFPA Temporary Interim Amendment 00–1(101) for incorporation by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. A copy of the amendment is available for inspection at the CMS Information Resource Center, 7500 Security Boulevard, Baltimore, MD and at the Office of the Federal Register, 800 North Capitol Street NW., Suite 700, Washington, DC. Copies may be obtained from the National Fire Protection Association, 1 Batterymarch Park, Quincy, MA 02269. If any additional changes are made to this amendment, CMS will publish notice in the **Federal Register** to announce the change.

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program).

(Catalog of Federal Domestic Assistance Program No. 93.778, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: September 1, 2004.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

Approved: December 7, 2004.

Tommy G. Thompson,

Secretary.

[FR Doc. 05–5919 Filed 3–24–05; 8:45 am]

BILLING CODE 4120–01–P

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI20

Endangered and Threatened Wildlife and Plants; Final Designation of Critical Habitat for Topeka Shiner

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule; correction.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce corrections to the final rule designating critical habitat for the Topeka shiner (*Notropis topeka*), published in the **Federal Register** on July 27, 2004. In the final rule, the map legends incorrectly referred to stream segments as ''proposed'' critical habitat rather than ''designated'' critical habitat, and six transcription errors were included in legal descriptions of critical habitat from Unit 1 (Iowa) and Unit 4 (Minnesota). This document corrects these errors.

DATES: Effective August 26, 2004.

FOR FURTHER INFORMATION CONTACT: Vernon Tabor, Kansas Ecological Services Field Office, 315 Houston Street, Suite E, Manhattan, Kansas 66502 (telephone 785–539–3474; facsimile 785–539–8567). The complete file for this correction document and the rule are available for public inspection, by appointment, during normal business hours at the above address. Copies of the rule, draft economic analysis, and draft environmental assessment are available by writing to the above address or by connecting to the Service

DAVE Tip Sheet

Section P1b, Therapies **March 2005**

Consistency Check Tips:

MDS Items:

- P1bcB – Physical Therapy Total Number of Minutes
- P1bbB – Occupational Therapy Total Number of Minutes
- P1baB – Speech-Language Pathology, Audiology Services Total Number of Minutes

Common Reasons for Discrepancies:

- Miscalculation of Therapy Minutes
- Including Initial Evaluation Time
- Treatment Time not Documented

Reference Source: RAI User's Manual, Version 2.0 June 2004, page 3–185 to 3-189.

The Data Assessment and Verification (DAVE) Project

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Assessment Guidelines

The ***Intent*** of Section P is to identify any special treatments, therapies, or programs that the resident received in the specified time period. For P1b, Therapies, include only skilled and medically necessary therapies furnished after admission to the nursing facility.

Errors in the coding of P1baB, P1bcB, and P1bbB, may be avoided if the following are taken into consideration:

1. Count only therapies that occurred after admission/readmission to the nursing facility, whether delivered in the facility or at another location, that were ordered by a physician, were performed by a licensed/qualified therapist and were medically necessary.
2. Only therapy services provided or directly supervised by a licensed/qualified therapist should be included; line-of-sight supervision by the licensed/qualified therapist is required to count the therapy aide and therapy student minutes.
3. The time required to adjust equipment or otherwise prepare for the individualized therapy of a particular resident is the set-up time and may be included.
4. The therapist's time spent on documentation may not be included.
5. Services provided at the request of the resident or family that are not medically necessary may not be counted.
6. Do not include group therapy minutes in excess of 25% of the total treatment time per discipline.

To Calculate Group Therapy Minutes:

1. Individual Minutes divided by 3 = Maximum Group Minutes
2. Individual Minutes Delivered + Group Minutes Delivered (Do not exceed Maximum Group Minutes from above) = Allowable Minutes for P1b

7. See page 3-188 of the RAI User's Manual for information on concurrent therapy/dovetailing.

Reason for Discrepancy	Coding Tips
Miscalculation of Therapy Minutes	a. Use a calculator to total the minutes. b. Double check your addition. c. Conversion from units to minutes is not appropriate. d. Do not round up or down. e. Do not count maintenance therapy once the program has been developed. f. Therapy minutes should only include actual, medically necessary minutes of skilled therapy received by the resident.
Including Initial Evaluation Time	a. Time spent on evaluations (including diagnostic audiology) **may not** be included. b. Include time spent on periodic medically necessary reevaluations during the course of ongoing treatment. c. Include set-up time.
Documentation that records the number of minutes is not provided or does not match the minutes coded on the MDS	a. Double check minutes documented in the clinical record (e.g. therapy log and treatment notes) against the MDS. b. Logs may be used to verify the provision of therapy services and to validate information reported on the MDS assessment. Logs are not an MDS requirement, but reflect a standard clinical practice expected of all therapy professionals.

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DAVE Tip Sheet

Common Reasons for Discrepancies:

P7—Physician Visits:

- Counting physician visits to the facility, when physician did not actually examine the resident
- Including exams that occurred in the emergency room
- Not using 14-day look-back period
- Omitting exams that occurred in the physician's office
- Omitting exams that occurred during dialysis or radiation treatments when there is a physician's progress note documenting the evaluation
- Miscalculation

P8—Physician Orders:

- Counting the number of orders versus the number of days
- Including admission orders, clarification orders or renewals without change
- Counting the different doses administered based on a written sliding scale dosage schedule
- Not using 14-day look-back period
- Omitting faxed orders
- Miscalculation

The Data Assessment and Verification (DAVE) Project

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DAVE e-mail: dave-project@csc.com

Section P—Special Treatments and Procedures **April 2005**
Item P7—Physician Visits
Item P8—Physician Orders

Assessment Guidelines

The ***Intent*** of Item ***P7—Physician Visits*** is to record the **number of days** during the last 14-day period a physician has examined the resident (or since admission if less than 14 days ago). Examination can occur in the facility or in the physician's office. For ***P8—Physician Orders***, record the **number of days** during the last 14-day period (or since admission if less than 14 days ago) on which a physician has changed the resident's orders.

Errors in the coding of P7 and P8 may be avoided if the following are taken into consideration:

1. The physical exam may be a partial or full exam at the facility or physician's office.
2. Include evaluations by physicians at dialysis or during radiation therapy, however, documenation of the evaluation should be included in the clinical record.
3. Include written, telephone, fax, or consultation orders for new or altered treatments.
4. Count only the initial order for a sliding scale dosage schedule.
5. If several physicians visit and write several different orders on that same day, code as 1 day for a physician visit and 1 day on which orders were changed.
6. Count only the initial PRN order currently on file. Do not include the notification to the physician that the PRN order was activated.
7. Do not include examinations by a physician during an unscheduled emergency room visit. (See Item P6)
8. Do NOT include standard admission orders, return admission orders, renewal orders, or clarification orders that do not note a change.
9. Do not count visits or orders prior to the date of admission or facility reentry.
10. A monthly Medicare certification is a renewal of an existing order and should not be included when coding.
11. Do not include orders for transfers of care to another physician or orders written by pharmacists.

Reference Source: RAI Manual, Version 2.0 June 2004, pages 3-204 and 3-205

If the Following Occurs	Then Cross-Check this MDS Item
If P7 and P8 are coded 2 or higher	Then the following MDS items should be reviewed for possible coding inconsistencies: • **I2**—Infections • **J2a**—Pain Frequency and **J2b**—Pain Intensity • **J5a** and **J5b**—Stability of Conditions • **M**—Skin Conditions • **O2**—New Medications • **P1a(a-l)**—Special Care and Treatments • **P9**—Abnormal Lab Values • **Q2**—Overall Change in Care Needs
If documentation in the clinical record reflects instability of a resident	Then the following MDS items should be reviewed for possible coding inconsistencies: • **I2**—Infections • **J1**—Problem Conditions • **J2**—Pain Symptoms • **J5**—Stability of Conditions • **M**—Skin Conditions • **O1**—Number of Medications • **O2**—New Medications • **O3**—Injections • **P7**—Physician Visits • **P8**—Physician Orders • **P9**—Abnormal Lab Values • **Q2**—Overall Change in Care Needs

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